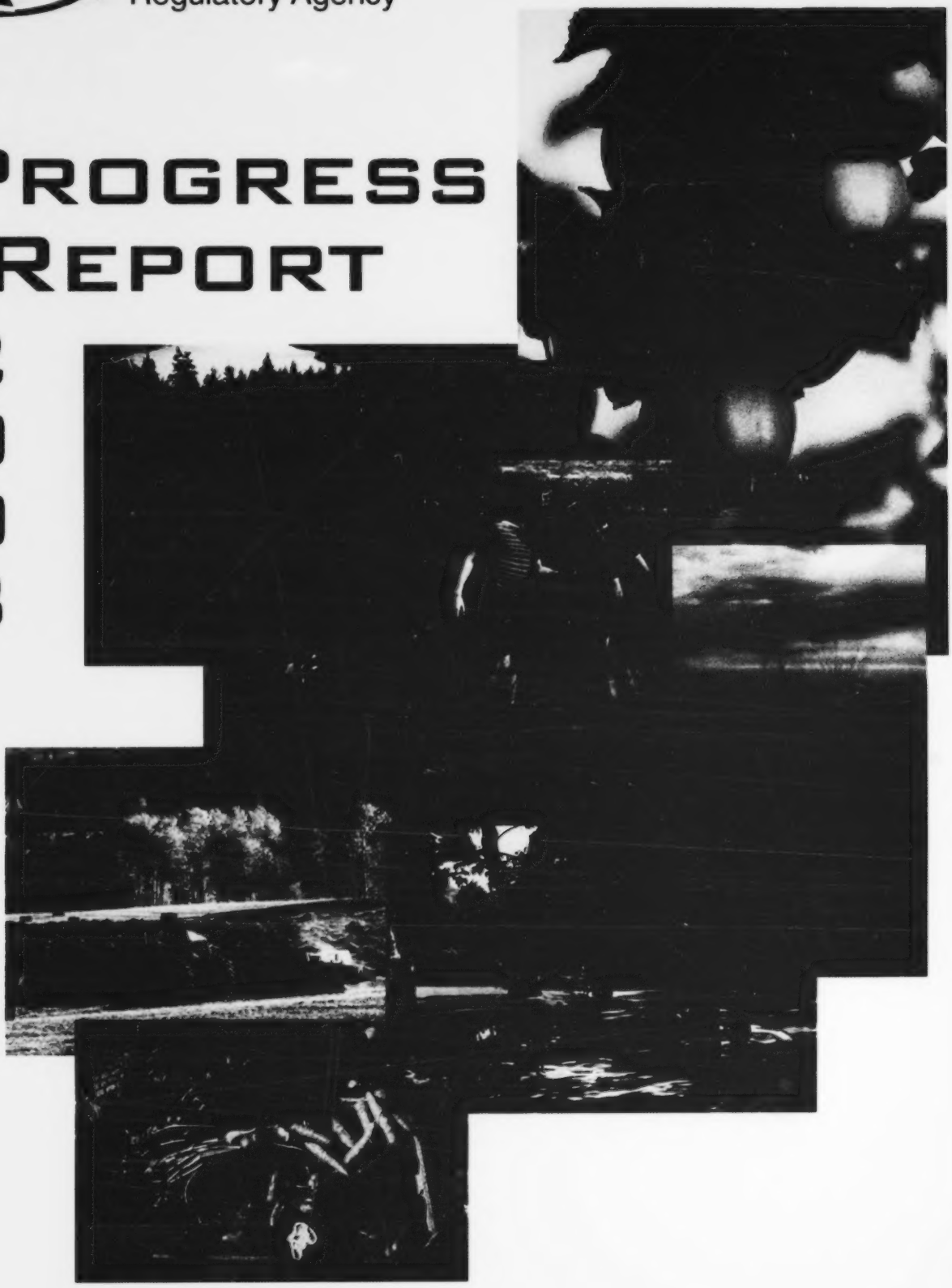
Pest Management
Regulatory Agency

PROGRESS REPORT 2003



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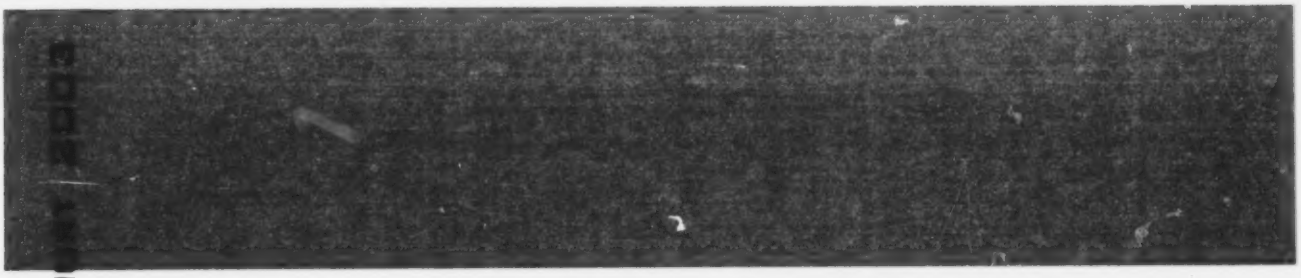

Pest Management Regulatory Agency Progress Report 1998–2003

Mission

To protect human health and the environment by minimizing the risks associated with pest control products, while enabling access to pest management tools, namely, these products and sustainable pest management strategies.

Vision

A regulatory agency widely respected in Canada and abroad for the quality of its decisions and its commitment to sustainable practices.

1998–2003 Progress Report

Pest Management Regulatory Agency Progress Repo

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Message from the Executive Director

Much has changed since Health Canada's Pest Management Regulatory Agency (PMRA) was created in April 1995. Many of the guidelines, directives and science policies have been updated and shared with our stakeholders, and we are well on our way to harmonizing our registration activities with our international counterparts. We have launched several cooperative initiatives with our stakeholders to ensure they are an integral part of our new policies and programs, including the Pest Management Advisory Council, the Economic Management Advisory Committee and the Federal/Provincial/Territorial Committee on Pest Management and Pesticides. In addition, we have worked to streamline and improve our internal processes.

The PMRA has set ambitious goals to enhance environmental protection and meet the needs of growers and our partners in the pesticide sector. We are confident this rigorous, comprehensive approach to pesticide regulation will help the Agency meet its commitment to protect human health and safety, while supporting best practices in Canadian and global pest management efforts.

Our overriding goals for the past five years have been:

- To protect health, safety and the environment from the risks of pesticides through the use of sound, progressive science, including innovative approaches to sustainable pest management.
- To meet the needs of Canadians for an open, transparent and participatory regulatory process, and for timely access to new, safer pest control products.
- To effectively manage human and financial resources.

In this, the PMRA's report on its five year strategic plan ending in 2003, we are pleased to present our program results to the end of March 2003.

Claire A. Franklin
Executive Director

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REGULATING PESTICIDES

The PMRA is responsible for protecting human health, safety and the environment by minimizing the risks associated with pesticides.

The PMRA regulates pesticides imported, sold or used in Canada nationally under two major federal statutes: the *Pest Control Products Act* (PCPA) and Regulations, and the *Food and Drugs Act* and Regulations. The PCPA provides authority to regulate the use of substances that claim to have a pest control use. It also regulates substances contained in pest control products, such as formulants, adjuvants and contaminants. The PMRA, on behalf of the Minister of Health, administers the PCPA, registering pest control products, re-evaluating registered products and setting maximum residue limits under the *Food and Drugs Act*.

Pest control products differ from many other substances that enter the environment as they are not by-products of a process; they are released intentionally for a specific purpose. Although their biological effects are what make most pest control products valuable to society, these effects can also pose risks to human and environmental health. For this reason, the PCPA and other policies affecting pesticides recognize and consider the environmental risks in addition to the human health risks and value of each product.

Pest control products have been closely regulated for many years. Consolidation of pesticide regulatory activities within the PMRA in April 1995, as well as planned revisions of the PCPA, will continue to strengthen the life-cycle management of pest control products in Canada.

The goal of the pesticide regulatory system is not only to prevent unacceptable risks, but also to minimize all risks posed by pest control products. Risk reduction efforts promote improvements in the handling and use of pesticides and the optimal management of pest problems. In June 1992, the United Nations Conference on Environment and Development helped launch international risk reduction efforts, and endorsed these plans as an important part of sustainable development.

Keeping the risks associated with pesticides to the lowest levels necessary to manage pest problems enhances sustainable pest management. The key is to provide health and environmental protection while maintaining the economic viability of users. Many countries find a systems approach, which considers all aspects of pesticides and all available ways to mitigate risks, to be the most successful.

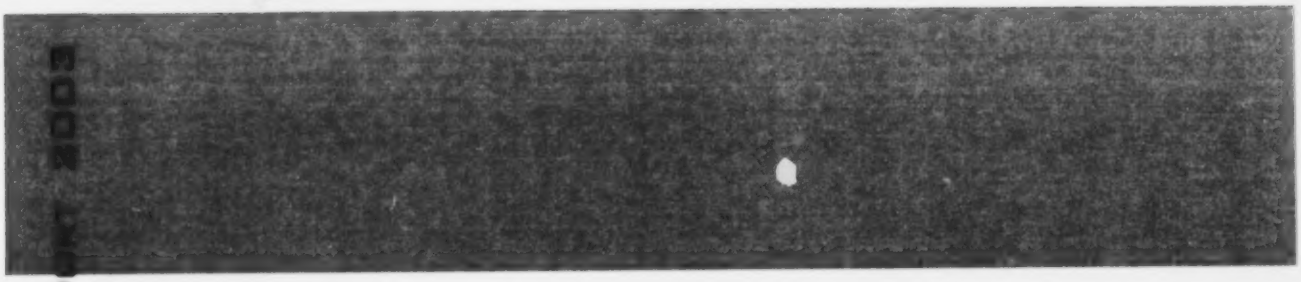
The PMRA manages the risks associated with pesticide use by:

- developing new policies and regulatory requirements that meet evolving international standards to reduce pesticide risks;
- supporting the development of sustainable pest management strategies;
- setting conditions of registration for new products;
- re-evaluating products that are already on the market; and
- monitoring compliance with conditions of registration.

Companies that wish to sell a pest control product in Canada must submit detailed information and data for evaluation by the PMRA. These companies provide all the scientific studies needed to determine if the product is acceptable in terms of safety, merit and value. Depending on the complexity of the submission, a complete evaluation can take several weeks, up to a year or longer. The evaluation determines whether the product is granted registration and allowed for sale and use in Canada, or is rejected. Pest control products are registered only if the human health and environmental risks are acceptable and the product is efficacious.

Before making a registration decision on a new pest control product, the PMRA conducts a comprehensive assessment of the risk and value specific to the proposed use. The value assessment considers whether the product contributes to pest management, and whether the application rates are the lowest possible to effectively control the target pest. The risk assessment considers the inherent toxicity, persistence and bioaccumulative nature of the pest control product, as well as potential hazards, including the level of exposure to humans and the non-target environment. Exposure estimates are a key component of the risk assessment process. As pest control products are deliberately introduced into the environment at quantifiable rates, potential short-term impacts of environmental exposures can be closely estimated. For long-term environmental exposure, the PMRA consults all available data on persistence and bioaccumulation.

For registered products, ongoing surveillance, analysis and re-evaluation safeguard against possible environmental or health concerns, particularly with older products.



THE PROVINCIAL/TERRITORIAL ROLE

Only pesticides that are registered for use under the PCPA may be imported into, or sold or used in Canada. The provinces and territories regulate the sale, use, storage, transportation and disposal of registered pesticides in their jurisdictions as long as the measures they adopt are consistent with any conditions, directions and limitations imposed under the PCPA or other federal legislation. For example, a province or territory may prohibit the use of a registered pesticide in its jurisdiction, or it may add more restrictive conditions on the use of a product than those established under the PCPA. It may not, however, authorize the use of a product that has not been approved under the PCPA and may not relieve the user of the obligation to comply with the conditions, directions and limitations imposed under the PCPA.

Provinces and territories administer a pesticide management program that includes education and training programs, the licencing and certification of applicators, vendors and growers as well as the issuing of permits for certain pesticide uses. Other important roles, often carried out in cooperation with PMRA regional offices, are those of enforcement and compliance monitoring, and response to spills or accidents.

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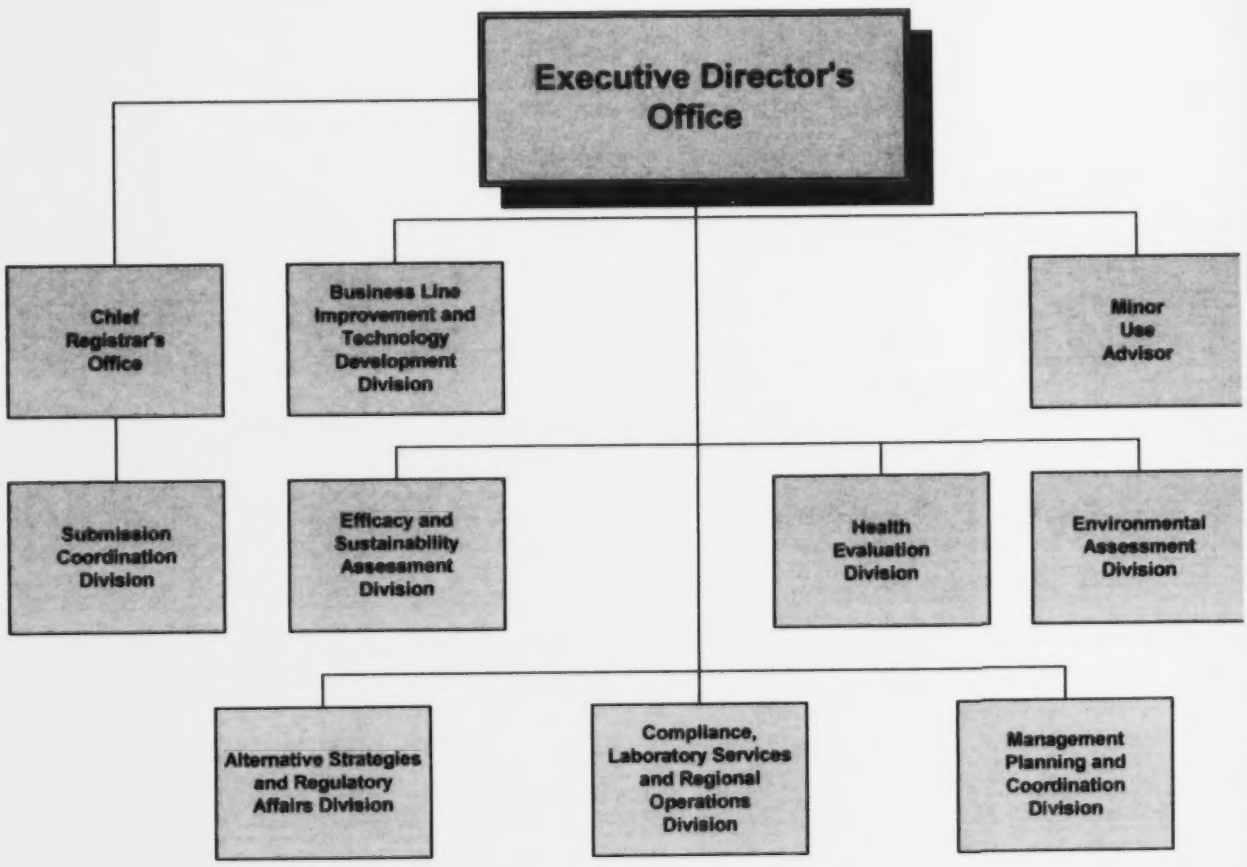
Organization of the PMRA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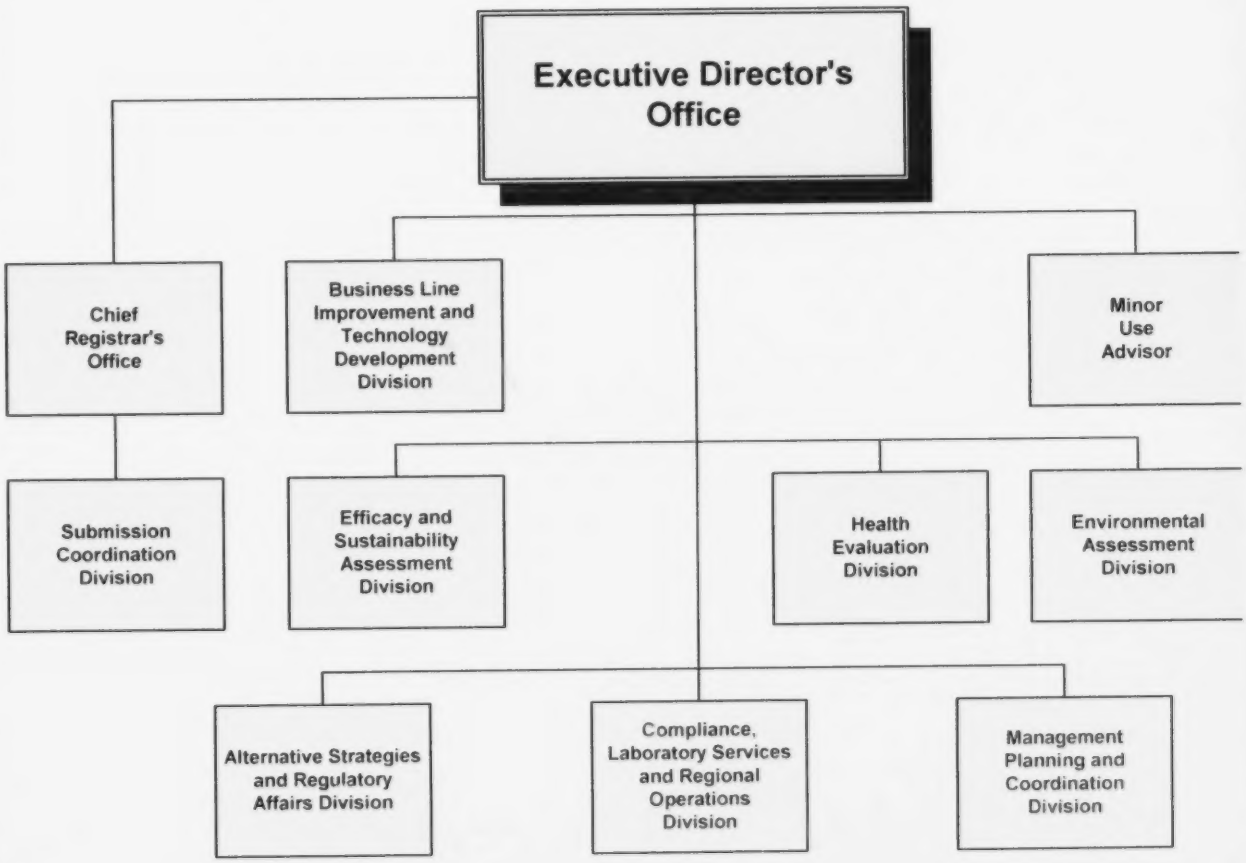
ORGANIZATION OF THE PMRA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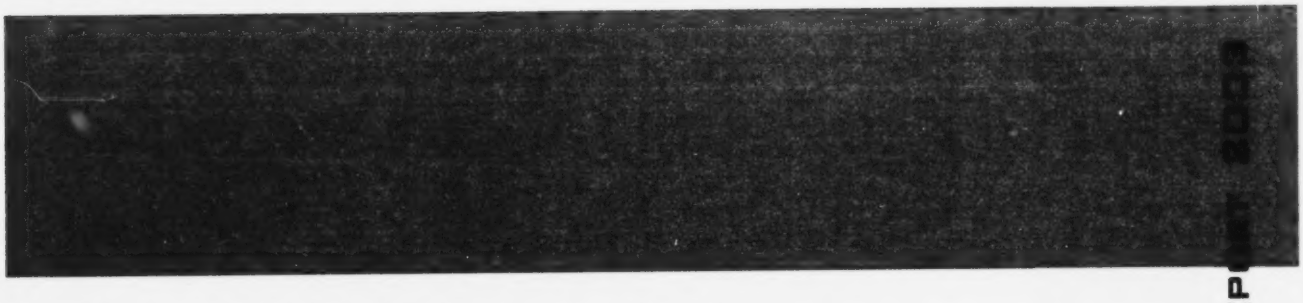


As of 31 March 2003, the PMRA is organized as follows.

Executive Director's Office

- oversees the operation of the PMRA; and
- chairs the Agency Management Committee (AMC), comprising the directors of all divisions.

Minor Use Advisor

- liaises with grower organizations, provinces, registrants, the United States Department of Agriculture's Interregional Research Project Number 4 (IR-4), and Agriculture and Agri-Food Canada (AAFC); and
- advises the PMRA on minor use issues, needs and developments.

Chief Registrar's Office

- ensures the PMRA makes integrated, science-based decisions in a timely fashion and in a global environment;
- manages registration, including minor use, and re-evaluation issues;
- chairs Science Review Committee meetings;
- co-chairs, with an industry representative, the Economic Management Advisory Committee;
- co-chairs, with a provincial representative, the Federal/Provincial/Territorial (FPT) Committee on Pesticides and Pest Management;
- provide secretariat support for external committees; and
- provides policy and strategic advice.

Submission Coordination Division

- manages and tracks submissions;
- conducts scientific screening of submissions;
- manages databases; and
- provides information services.

Business Line Improvement and Technology Development Division

- directs business line improvement projects, including electronic environment initiatives; and
- provides information technology support.

Efficacy and Sustainability Assessment Division

- provides expertise on the use of antimicrobials, fungicides, herbicides, insecticides and other pesticides; and
- houses a team of scientific evaluators conducting efficacy assessments, sustainability evaluations and value assessments for pest control products.

Health Evaluation Division

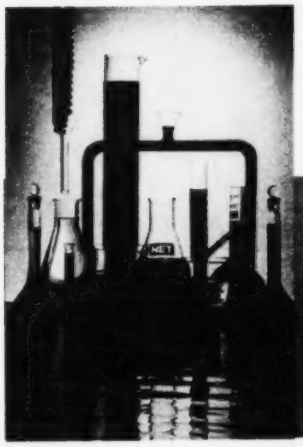
- provides expertise on human health hazards, risk assessments and risk mitigation;
- houses a team of scientific evaluators conducting toxicology evaluation and exposure assessment of pest control products; and
- participates in national and international activities to harmonize testing and evaluation procedures.

Environmental Assessment Division

- provides expertise on environmental hazards, risk assessments and risk mitigation;
- houses a team of scientific evaluators conducting assessments of the environmental fate and effects of pest control products; and
- participates in national and international activities to harmonize testing and evaluation procedures.

Alternative Strategies and Regulatory Affairs Division

- develops policies, programs and projects related to sustainable pest management and coordinates national and international activities;
- directs the development, review and assessment of policies, regulations, programs and legislative amendments;
- liaises with other federal government departments through individual Memoranda of Understanding and with stakeholders through the Integrated Pest Management projects;
- houses the Continuous Learning Program;
- prepares and implements strategic communications plans for the PMRA;
- publishes regulatory documents;
- handles Access to Information requests; and
- manages the reference centre.



Compliance, Laboratory Services and Regional Operations Division

- enforces the PCPA;
- conducts national pesticide compliance inspections and investigations;
- represents the PMRA at the local level;
- provides expertise on the chemistry of pest control products and analytical testing;
- conducts product chemistry evaluations; and
- conducts analytical testing of samples associated with investigation and inspection programs.

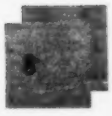
Management Planning and Coordination Division

- manages the financial aspects of cost recovery;
- provides financial and general administration; and
- houses information management and human resources services.

Of our more than 400 employees, a majority are scientists who evaluate every aspect of pest control products: from their chemistry, efficacy and health and environmental effects, to their place in Canadian forestry, agricultural and domestic sectors. Our scientists are members of dozens of professional associations and institutes, and are recognized nationally and internationally as experts in their fields. They provide a wealth of experience in many disciplines, including human and environmental toxicology, biology, microbiology, chemistry, entomology, agronomy, parasitology, zoology, weed science, occupational hygiene and agriculture. Their research has been widely published in scientific journals and has garnered many awards.

Our support staff make possible the day-to-day operations of the Agency: managing communications, administrative services, training, human resources, financial administration and information systems.

The Agency's laboratory is accredited by the Standards Council of Canada under the stringent ISO/IEC 17025 requirements. The laboratory's high level of achievement has been recognized with two awards for excellence.



INVOLVING OUR PARTNERS

INTERNATIONAL COOPERATION

Pesticide regulatory agencies and industry recognize that efficiency and effectiveness are maximized through international collaborative efforts. The PMRA works closely with two groups to advance international cooperation (harmonization) in pesticide regulation—the North American Free Trade Agreement Technical Working Group on Pesticides (NAFTA TWG) and the Organisation for Economic Co-operation and Development Working Group on Pesticides (OECD WGP).

HARMONIZATION

Harmonization requires a complete understanding of the methods and practices used to regulate pesticides in other countries, and the willingness of everyone involved to merge these approaches. This does not mean setting standards to the lowest common denominator, or simply accepting another country's decision, but rather finding an acceptable middle ground that maintains our current high level of protection of human health and the environment. When agreement cannot be reached, the differences are clearly defined. Canada is pursuing a wide range of initiatives with the United States (U.S.) through the NAFTA TWG and with other countries through the OECD WGP.

The PMRA works with its international counterparts in North America and abroad to harmonize regulatory approaches. The results of harmonization can provide the basis for a more efficient system that facilitates registration of safer and more effective pesticides. Because countries are working together, it is possible to promote sound regulatory policies worldwide. Harmonization benefits everyone by increasing the use of work completed by other countries, thereby reducing the work of reviewing new and existing pesticides. Regulatory agencies see increased efficiency through work sharing initiatives and joint reviews. The pesticide industry benefits from reduced submission costs, and faster and broader access to international markets. Growers in all countries have faster and more equitable access to a wider range of more effective pest control products, and public safety is enhanced as newer and safer products are introduced.

The goal of harmonization is to standardize:

- the type and scope of studies required to register or re-evaluate a pesticide;
- the protocol followed in carrying out these required studies;
- the format and presentation of manufacturers' submissions for registration (dossier);
- the methods used to evaluate submissions and prepare country reports (monograph); and
- the methods used to transmit and archive submissions and country reports
- the methods used to carry out risk assessments.

NORTH AMERICAN FREE TRADE AGREEMENT

To improve cooperation, information and work sharing between Canada, the U.S. and Mexico, the NAFTA TWG was established in March 1996. The primary objective of the NAFTA TWG is to foster cost-effective pesticide regulation among its member countries—Canada, the U.S. and Mexico. It also recognizes the broader NAFTA objectives of environmental protection and sustainable development. At its meeting in June 1997, the NAFTA TWG agreed that work sharing should become routine within five years. A document entitled the *North American Initiative* provides the conceptual framework for the work of the NAFTA TWG, which hopes to establish a North American Market for pesticides and make work sharing between Canada and the U.S. a routine part of business by 2002. The working group achieves its impressive results through joint projects under its subcommittees: Food Residues, Joint Review, Risk Reduction, and Regulatory Capacity Building.

The Agency has participated in a number of NAFTA and OECD projects to harmonize data requirements for pesticide submissions, to develop common study protocols (test guidelines) and common formats (dossiers) including electronic approaches for submissions by registrants, to develop common formats including electronic approaches for the review of submissions (monographs), to share reviews, and to harmonize risk assessment/risk management procedures. More information on these projects is available at http://www.hc-sc.gc.ca/pmra-arla/english/intern/intern-e.html.

Information on international harmonization efforts under the NAFTA TWG is circulated in meeting and progress reports, updates and summary records. Stakeholders are consulted prior to the yearly full meeting of the NAFTA TWG.

The PMRA and the United States Environmental Protection Agency (USEPA) established a Joint Review Program for reduced-risk pesticides in 1996. Since then, the program has expanded to include other types of pesticides that qualify as organophosphate alternatives or NAFTA priority chemicals (e.g., methyl bromide alternatives) as well as a third category for other pesticide submissions including those that may be in OECD format or an electronic submission. Under this program, the PMRA and USEPA review different sections of a submission and exchange reviews as they are completed. A reduced time line of 12 months for reviewing complete joint data submissions that are considered reduced risk with one active and two end use products has been established. Ways to involve Mexico in joint review activities continue to be sought; the focus to date has been on capacity building.

Organisation for Economic Co-operation and Development

Thirty member countries meet through the OECD WGP to share the work of pesticide evaluation, to minimize non-tariff trade barriers and to reduce risks to human health and the environment. Frequently, there are opportunities to cooperate with a broader range of countries on NAFTA TWG projects through the OECD WGP.

A key accomplishment resulting from OECD harmonization activities is the development of international standards for submission formats. The PMRA accepts submissions formatted according to the *Guidelines and Criteria for Industry for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for Plant Protection Products and their Active Substances in Support of Regulatory Decisions in OECD Countries* dated March 2001, found on the OECD website http://www.oecd.org/, at http://www.eddenet.ca as well as through links via the PMRA website http://www.hc-sc.gc.ca/pmra-arla. This OECD format contains a crosswalk of numbering systems (e.g., OECD, European Union [EU], U.S., Canada, Japan, Australia) for organizing and indexing supporting data. The PMRA will also accept applications for microbials and pheromones submitted in the recently developed OECD format (2003), available at the same OECD website.

Another accomplishment is the OECD database that contains information on the status of country reviews and registrations, available only to OECD-member countries. This serves to facilitate work sharing by allowing countries to identify what reviews might be available. In addition, countries are beginning to look for opportunities to more actively workshare across regions, for example between Canada and the European Union.

Other International Partners

The PMRA contributes to other international bodies, including the Intergovernmental Forum on Chemical Safety, the Codex Committee on Pesticide Residues, the Prior Informed Consent procedure under FAO/UNEP, the North American Commission for Environmental Cooperation, the United Nations Economic Commission for Europe Convention on Long-Range Trans-boundary Air Pollution, and the Marine Environmental Protection Committee of the International Marine Organization.

Our Canadian Partners

The Pest Management Advisory Council

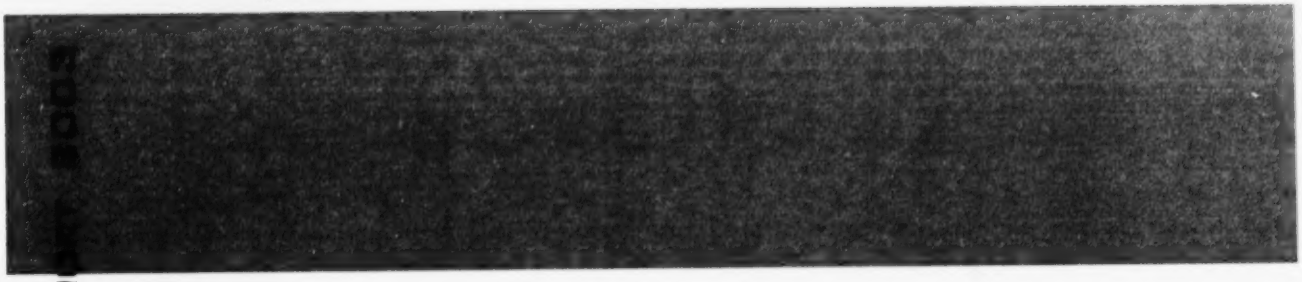
The Pest Management Advisory Council (PMAC), formed in 1998, serves as a forum to foster communication and dialogue among stakeholders and the PMRA as well as to provide advice to the Minister of Health on policies and issues relating to the federal pest management regulatory system. In order to achieve a balanced representation of interests in pest management issues, PMAC's membership includes environmental, health and consumer groups as well as academics and pesticide manufacturers and users. The Council has met regularly during the last five years and has provided valuable advice to the Minister. The Council's advice was particularly important in shaping the new *Pest Control Products Act*. More information on PMAC is available at http://www.hc-sc.gc.ca/pmra-arla/english/advbod/pmac-e.html.

The Economic Management Advisory Committee

The Economic Management Advisory Committee (EMAC) was established in April 1997 to provide strategic advice to the PMRA's Executive Director on specific ways to improve efficiency and cost effectiveness without compromising health or environmental protection and while maintaining industry competitiveness. EMAC membership includes pesticide industry representatives, grower groups and officials from the PMRA. Additional information about EMAC is available at http://www.hc-sc.gc.ca/pmra-arla/english/advbod/emac-e.html.

Federal/Provincial/Territorial Committee

The Federal Provincial Territorial (FPT) Committee on Pest Management and Pesticides, formed in 1997, brings together provincial, territorial and federal representatives on pesticide use, regulation and management to exchange information and expertise. The FPT Committee provides advice and direction to governments on programs, polices and issues relating to pesticides, and actively pursues solutions to shared concerns through the activities of its working groups. The FPT Committee working groups are addressing key pesticide issues: product classification, buffer zones, pesticide indicators, education training and certification, and healthy lawns (http://www.hc-sc.gc.ca/pmra-arla/english/fpt/fpt-e.html).



FEDERAL PARTNERS

A number of departments are involved with pest management at the federal level. Relationships between the PMRA and federal colleagues have been described in Memoranda of Understanding. Agreements exist with colleagues in other parts of Health Canada, with Environment Canada, Fisheries and Oceans, the Canadian Food Inspection Agency (CFIA) as well as Agriculture and Agri-Food Canada (AAFC).

A federal Working Group on Pesticides and Pest Management has been formed to coordinate, promote and foster closer cooperation among the scientists and regulators working on pesticide and pest management issues at the participating federal departments (Environment Canada, Fisheries and Oceans, Natural Resources Canada, CFIA, AAFC and Health Canada). This cooperation will allow for better, science-based decision making in the process of registering and managing pesticides. The working group is assessing research gaps and regulatory needs, to make recommendations for additional research.

PMRA ARLA

THE NEW PEST CONTROL PRODUCTS ACT

The new *Pest Control Products Act* (PCPA) received Royal Assent on 12 December 2002, and will come into force on a date yet to be determined. The Act will replace the existing *Pest Control Products Act* enacted in 1969, and is the culmination of more than ten years of consultation.

The new Act will strengthen health and environmental protection by requiring special protection for infants and children. It will take into account pesticide exposure from all sources, including food, water and residential use, and consider cumulative effects of pesticides that act in the same way. The new Act will also support pesticide risk reduction, for example, by ensuring that only pesticides that make a useful contribution to pest management are registered and expediting the registration of lower-risk products.

Moreover, post-registration control of pesticides will be strengthened by requiring pesticide companies to report adverse effects. The new Act will require re-evaluations of older pesticides 15 years after they are registered and provide the Minister with the authority to remove pesticides from the market if required data are not supplied. It provides increased powers of inspection and higher maximum penalties, up to $1 million for the most serious offences.

The new Act will also make the registration system more transparent by establishing a public registry to allow access to detailed evaluation reports on registered pesticides and allowing the public to view the test data on which these pesticide evaluations are based. The new PCPA will allow the PMRA to share data evaluation reports with international regulators, which will enhance the process for international work sharing of pesticides, and enhance harmonization so that Canadian growers equal access to newer, safer pesticides so they can be competitive in the marketplace.

PUBLIC PARTICIPATION

The current *Pest Control Products Act* does not provide any formal mechanism for the public to participate in the decision-making process prior to registration of a pest control product. The PMRA has provided opportunities for the public to participate in decision making, through implementation of a policy to consult on proposed decisions for full registration of a new active ingredient if the application was received after 1 April 1995. The PMRA must have permission from the applicant before the consultation document is released publicly.

Comments on proposed guidelines have been invited through the publication of Regulatory Proposals. Other information services provided to the public have included Backgrounders, Discussion Papers, Regulatory Directives, Regulatory Notes, Fact Sheets, newsletters and a toll-free Pest Management Information Service.

Under the new PCPA, the regulatory system will be more open to public participation through a program of public consultation complemented by public access to information. Codifying public participation in the new Act will create certainty and predictability for stakeholders and the general public.

Adoption of New Science Policies

New science policies to reduce pesticide risk have been developed and implemented by the PMRA in concert with the USEPA. In the U.S., these policies have resulted from the new *Food Quality Protection Act*. In the past, the PMRA has participated in activities of the U.S. Tolerance Reassessment Advisory Committee, which established a framework for the development and implementation of the policies. The PMRA continues to work with the new U.S. Committee to Advise on Reassessment and Transition, which has replaced the Tolerance Reassessment Advisory Committee. The PMRA was involved during the development of the U.S. science policies and provided comments on the U.S. draft reports. These approaches to risk management, which represent how, as much as is possible, the PMRA carries out risk assessment now, are embodied in the new PCPA.

The key elements are:

1. Safety margins
   For threshold effects, an additional tenfold margin of safety for infants and children must be used for exposure to the pesticide chemical residue in foods and other sources. This takes into account potential pre- and post-natal toxicity, and also the completeness of data on exposure and toxicity in infants and children. A different margin of safety may be used only if reliable data confirms it will be safe for infants and children.

2. Aggregate risk
   Available information on aggregation of exposure from a single pesticide must be considered. This includes dietary and drinking water exposure and other non-occupational exposures, such as use in homes and schools.

3. Cumulative effects
   Available information on cumulative effects of pesticide chemicals with common mechanism of toxicity must be considered.

The PMRA has published a number of the science policies and continues to work closely to harmonize with the USEPA where appropriate. More information can be found at http://www.hc-sc.gc.ca/pmra-arla/english/pubs/fqpa-e.html.

Toxic Substances

In March 1999, the PMRA became the first federal government organization to establish a plan to address the requirements of Canada's Toxic Substances Management Policy (TSMP). The TSMP was released in 1995 to guide the management of toxic substances and other substances of concern released into the environment. It calls for the virtual elimination of Track 1 substances (those that are toxic, or equivalent, under the *Canadian Environmental Protection Act*, predominantly anthropogenic, persistent and bioaccumulative), and for the full life cycle management of Track 2 substances to prevent or minimize their release. For more information about the TSMP, please see: http://www.ec.gc.ca/toxics/en/index.cfm.

When introducing its *Strategy for Implementing the Toxic Substances Management Policy* (http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir9903-e.pdf) in 1999, the PMRA started to ensure that all newly registered pesticides were free of Track 1 substances, either as active ingredients or as micro-contaminants. No substances on the federal government's list of Track 1 substances are registered as active ingredients in pesticides, and the PMRA is systematically evaluating currently registered active ingredients to identify those, if any, that meet the TSMP criteria and should be designated as Track 1 substances.

The strategy also aimed to virtually eliminate micro-contaminants (including dioxin and frans, in particular 2,3,7,8-substituted and hexachlorobenzene) in those pesticides that were first registered before TSMP was introduced. Micro-contaminants can result inadvertently when pesticides are being manufactured. The PMRA has been working with registrants toward the virtual elimination of these micro-contaminants. A number of action plans have been received from registrants and best available technology targets will be set.

Reduced-risk Products

Risk can be limited through the use of new biopesticides and reduced-risk chemical pesticides. The earliest chemical pesticides were formulated for effectiveness against a broad spectrum of pests. This broad spectrum efficacy can destroy both beneficial and harmful organisms. Biopesticides such as pheromones and microbials—which have a narrow range of activity and low persistence—can contribute to more sustainable pest management systems in several ways:

- minimize adverse impacts on predators and parasites of pests, thus allowing these beneficial organisms to reduce pest populations;

- suppress pest populations to levels low enough for alternative management practices, such as crop rotation or physical barriers, or to allow reduced rates or frequency of application of conventional pesticides; and
- provide a viable alternative to existing products.

The Agency recognized the need to encourage registration of new reduced-risk pesticides early on, and continues to work with a variety of stakeholders to improve access to these alternative products as well as to encourage manufacturers to submit them for registration in Canada. The PMRA has, in large measure, harmonized its data requirements with the U.S. and uses a joint review process for reduced-risk chemicals and biopesticides. This process provides for reduced review timelines for new, reduced-risk products. Joint review provides for reduced evaluation time for these products, and simultaneous access to the Canadian and U.S. markets.

These established reduced-risk programs facilitated market access for reduced-risk products to the North American market; however, they did not address registration of products that were already registered in the United States before the creation of the Reduced-risk Joint Review Programs. In May 2002, the PMRA introduced an initiative to address this situation.

The PMRA Initiative for Reduced Risk Pesticides (http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir2002-02-e.pdf) was extended to include priority review for reduced-risk products that were already registered in the United States but for which no Canadian application had been made. The program is designed to encourage pesticide manufacturers to apply for Canadian registration of reduced-risk products that are currently available in the U.S.

To minimize the barriers to these products, Canada is using the same criteria as the USEPA to determine eligibility of chemicals for the reduced-risk program and recognizes the USEPA's biopesticide designation, thus further harmonizing the respective approaches of the two countries. Through this program, the PMRA also committed to shorter review timelines for products that have been shown to qualify as reduced-risk chemicals or biopesticides.

Biopesticide products are often very specific to target pests, which means the potential market will not be as large as for traditional broad-spectrum chemicals. As a result, microbials and semiochemicals were exempted from fees for scientific review when Cost Recovery Regulations were established in

April 1997. Products that are not microbials or semiochemicals may also qualify for a fee reduction based on low potential sales.

The PMRA, in its continued support of reduced-risk products and international efforts to harmonize common core data requirements, led the OECD Biopesticides Steering Group in the following activities:

- overseeing microbial, pheromone and invertebrate biological control agent work,
- hosting an OECD workshop on data requirements for pheromones,
- initiating work on harmonizing data requirements for microbials; and
- completing the work of harmonization of data requirements for microbials, pheromones and invertebrate biological control agents, and of development of dossier and monograph formats for both microbials and pheromones.

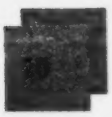
For more information, see http://www.hc-sc.gc.ca/pmra-arla/english/intern/oecd-e.html.

Maximum Residue Limits for Food

The setting of maximum residue limits (MRLs) ensures that total consumption of the residue of a pesticide from all food uses, including food produced in Canada or imported from other countries, will not exceed the acceptable daily intake for that pesticide. They are based on the maximum amount of residue that may remain in food, at the point of sale, when a pesticide has been applied. MRLs are established for all types of food: fruit and vegetables, including juices, meat, dairy products, grains and processed foods. Depending on the pesticide and the food commodity, allowable residues can range from a fraction of a part per million to several parts per million.

Through international organizations such as the United Nations Food and Agriculture Organization, the PMRA cooperates with other countries to develop international standards for residue levels.

PMRA Regulatory Directive DIR98-02, *Residue Chemistry Guidelines* (http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir9802a-e.pdf), published in June 1998, describes the scientific data required with respect to residues in food, for an application to register an agricultural chemical in Canada. Harmonized for NAFTA countries, the document explains the requirements regarding the qualitative and quantitative nature of the residues in plant and animal foods. In addition to scientific data requirements, these guidelines provide guidance on the criteria and protocols for the design, performance and validation of



scientific studies, and for reporting scientific data. The data in these studies allow PMRA scientists to assess the validity of each study and to clarify the nature and quantity of residues in treated foods. The guidelines, which are harmonized with U.S. guidelines, were developed in consultation with stakeholders. Requirements were phased in to give industry adequate time to perform studies according to the guidelines.

The guidelines give instructions on gathering supervised, crop field trial data from defined regions or zones (identified on Geographical Information System maps). Where these zones are designated the same in Canada, the U.S. or Mexico, residue data generated within the same zone in one country is valid within the other country. The zone maps reduce the need for industry to provide country specific data.

Maximum Residue Limits and 0.1 ppm Default MRL

In January 2003, the PMRA issued a proposal to amend Division 15 of the Food and Drug Regulations, Regulation B.15.002(1), and to revoke the 0.1 ppm General Maximum Residue Limit. The General Maximum Residue Limit is also called the default level for pesticide residues on food. A food is adulterated if it contains residues of a pesticide at or above this default level, unless a specific MRL has been established in the Food and Drug Regulations. The PMRA has proposed to replace the default level by setting specific MRLs for each pesticide and food combination, whether the food is produced domestically or imported.

The continued reliance on the default approach for low level residues has been re-examined because both Canada and the U.S. have recently adopted more stringent safety standards, including use of additional safety factors, aggregation of exposure to pesticide residues in all media, and assessment of cumulative risk for pesticides that have a similar mode of toxic action. These features are embodied in the American *Food Quality Protection Act* and in the new PCPA.

The use of the default level for domestic and imported food commodities legally allows unnecessarily high levels of pesticide residues in food, as today's good agricultural practices result in actual residue levels that are significantly below the default level.

Among major developed countries, Canada is one of a very few to continue to rely on a 0.1 ppm default level. The proposed setting specific MRLs for each pesticide and food combination would bring Canada in line with worldwide regulatory practices for setting MRLs.

The proposed revocation of Regulation B.15.002(1) would be a significant change to the current regulatory system. The January 2003 proposal gave all stakeholders an opportunity to evaluate the impact and consequences of the proposed change, and to provide their comments to the Agency. The comments received from stakeholders are currently being analyzed.

Test Guidelines for Monitoring Postapplication Exposure

There is concern over postapplication exposure to pesticides, both in the agricultural and residential environments. Concerns from exposure to agricultural pesticides first began to be raised during the 1950s and 1960s as many of the environmentally persistent organochlorine insecticides (generally of low acute toxicity) began to be replaced with less persistent, but often acutely toxic, compounds.

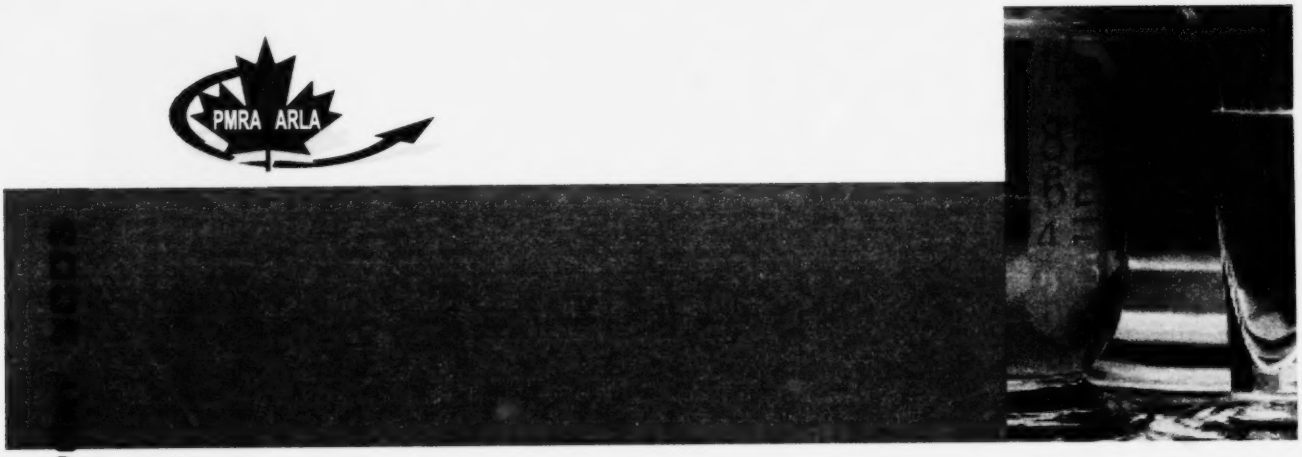
As this transition to more acutely toxic pesticides occurred, workers entering treated fields to cultivate or harvest crops were, on rare occasions, subjected to exposures at levels capable of producing illness or even death.

Historically, concerns associated with the use of pesticides have focused primarily on agricultural environments. However, in recent years the use of pesticides in indoor and residential environments has escalated, initiating a cause for increased attention to pesticide exposures in these environments.

In September 1998, the Agency published its proposed harmonized *Postapplication Exposure Monitoring Test Guidelines* (http://www.hc-sc.gc.ca/pmra-arla/english/pubs/pro9804-e.html). Under the Regulatory Capacity Building Subcommittee of the NAFTA TWG, the USEPA, the PMRA and the California Department of Pesticide Regulation developed a harmonized guideline, based on the draft USEPA Series 875 document, *Occupational and Residential Exposure Test Guidelines - Group B - Postapplication Exposure Monitoring Test Guidelines*. The PMRA guideline gives direction for designing and implementing studies required to assess postapplication exposure.

Formulants

In the final report (December 1990) of the Pesticide Registration Review Team, recommendations for a revised federal pest management regulatory system were proposed. One of these recommendations was the development of a Formulants Policy for the regulation of formulants. This would include the development of an up-to-date list of formulants used in Canada, the categorization of formulants in accordance with a specified classification scheme, and the provision of options for regulatory actions on these formulants.



A formulant is defined as any substance other than the active ingredient that is intentionally added to a pest control product to improve its physical characteristics (e.g., sprayability, solubility, spreadability, stability). In spring 2000, the Agency published Regulatory Proposal PRO2000-04, *Formulants Policy* (http://www.hc-sc.gc.ca/pmra-arla/english/pdf/pro/pro2000-04-e.pdf), for public comment. After considering comments received, the Policy was revised and will soon be released as a Regulatory Directive. The policy outlines how formulants in pest control products will be regulated. It represents the government's implementation of the Pesticide Registration Review recommendations with respect to formulants. Furthermore, the policy is based on the approach of the USEPA, and is another step towards harmonization of pesticide regulation.

As part of its policy on the regulation of formulants, the Agency has categorized formulants found in pest control products registered in Canada based on level of concern with respect to human health and the environment. The resulting five lists are similar in structure to those of the USEPA Lists of Inert Ingredients; they were developed, using the same criteria as the USEPA, with some additional Canadian criteria resulting from legislative and policy requirements. List 1 includes formulants of toxicological concern (as on the current and previous USEPA Inert List 1), those meeting criteria of the federal TSMP and those subject to the Montreal Protocol of ozone-depleting substances. List 2 contains formulants considered to be potentially toxic. List 3 contains formulants that do not meet criteria for the other lists. List 4A formulants are of minimal toxicologic concern. List 4B contains formulants of minimal concern under specific conditions of use. A list of all formulants (PMRA List of Formulants) that are found in pest control products currently registered in Canada will be published as a separate document.

Current List 1 formulants are to be phased out of all control products by 31 December 2004. As of 31 December 2002, only products for which registrants have already provided safety data to support the continued use of a List 1 formulant or made an application to replace the List 1 formulants could be sold.

List 2 formulants, formulation preservatives and allergens known to cause anaphylactic type reactions, will be subject to disclosure labelling, as required by the new PCPA.

The Formulants Policy is in the final stages of the review and publication process.

PRODUCT CHEMISTRY

Product chemistry information is developed and submitted for review to meet two objectives.

(a) To identify and quantify the active ingredient(s) for purposes of the pest control product's certified limits.

(b) To comprehensively identify product composition, including active ingredient(s), impurities and formulants, in order to:

(i) determine the uniqueness of each source of product with regard to purity and potency; and

(ii) assess the safety to humans and the environment under the proposed use of the product.

Chemistry Requirements for Registration of a Technical Grade of Active Ingredient or an Integrated System Product (http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir9804-e.pdf), published in May 1998, details the chemistry requirements for registration under the PCPA and Regulations, and the recommended organization of Part 2 of the data submission. Guidance is also provided on the submission of product-related analytical standards. The revision process sought industry input through a Regulatory Proposal published in July 1997, after a public comment period. The chemistry requirements have been harmonized with those of the USEPA.

Chemistry Requirements for the Registration of a Manufacturing Concentrate or an End-Use Product Formulated from Registered Technical Grade of Active Ingredients or Integrated System Products (http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir9803-e.pdf), published in May 1998, details the chemistry requirements for registration under the PCPA and Regulations and the recommended organization of Part 3 of the data submission.

MITIGATION OF ENVIRONMENTAL EFFECTS: OFF-TARGET DEPOSIT

The PMRA and the USEPA have worked together through a NAFTA TWG project on computer models that provide a more accurate assessment of potential off-target drift and deposit of pesticides. In 1998, PMRA environmental evaluators began using a computer model to assess spray drift and deposit from the aerial application of pesticides in agriculture and forestry. The of a model can more accurately predict spray

drift and, subsequently, the established buffer zones are more precise. This reduces the need for expensive field studies, saving time and resources for industry and the Agency.

Label Improvement

On 19 December 2001, *Regulations Amending the Pest Control Products Regulations* were published in the *Canada Gazette* Part II. This amendment to the Regulations specified that as of 1 January 2003 all pest control products whose registration is granted, amended or renewed after this date must have a bilingual (English and French) product label. There are two exemptions to the regulations:

(a) Until 1 January 2008, if the label language of a registered control product is not already bilingual, the label language of an emergency use registration for this product is exempt from the bilingual labelling requirement.

(b) Product labels of registered products that are not manufactured, imported, sold or used in Canada may be in either English or French, or both.

The PMRA is consulting the provinces, territories and stakeholders to upgrade the quality, consistency and accuracy of product labels. These efforts help amend the conditions of use of the products, to improve their compatibility with integrated pest management and pesticide resistance management programs.

To ensure consistency in pesticide grouping and labelling, and to contribute to the management of the pesticide-resistance problem, the PMRA published *Voluntary Pesticide Resistance-Management Labelling Based on Target Site/Mode of Action* (http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir9906-e.pdf) in 1999. The document outlines the joint approach by Canada and the U.S. to pesticide resistance-management labelling. Through this initiative, information will be included on the label for growers to reduce pesticide resistance, and joint registration decisions will be supported.

Good Laboratory Practice

The OECD Good Laboratory Practice (GLP) covers the process and conditions under which non-clinical laboratory and field studies are planned, conducted and reported. It is designed to promote the quality and validity of test data, and to improve the international acceptance of data, because of adherence to its principles. GLP applies to all testing of pest control products to obtain data on their properties and/or safety with respect to human health or the environment.

In July 1998, the PMRA introduced its GLP requirements in Regulatory Directive DIR98-01, *Good Laboratory Practice* (http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir9801-e.pdf). This document was preceded by a Regulatory Proposal, published for public comment in October 1996. GLP requirements were phased in for an orderly transition. GLP requirements are part of the Agency's harmonization initiative, an effort to share the burden of the registration process with other OECD-member countries through the exchange of reviews based on mutually acceptable studies.

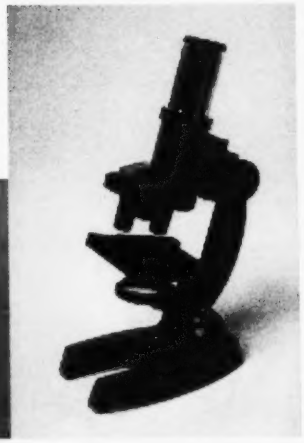
The Agency worked closely with the Standards Council of Canada in 1998 and 1999 to establish a GLP Compliance Monitoring Authority under the auspices the Standards Council of Canada. The first GLP recognitions were granted by the Council in July 1999 and there are now 24 recognized field sites/test facilities. The PMRA served as Convenor of the Council's GLP Working Group from its inception until April 2003.

The PMRA and USEPA signed a Memorandum of Understanding in 1999 regarding the reciprocal recognition of each party's established GLP program for pesticide products. As required for full implementation of the Memorandum of Understanding, the evaluation of each other's inspection and audit procedures was completed in 2000, leading to a letter of confirmation signed by both parties in November 2000.

Research Permits

Research is essential in the development of pest control products. Only well-documented research provides the scientific and technical information needed to evaluate the efficacy and safety of a product. The PCPA provides opportunities for research under conditions set out in the Pest Control Products Regulations.

The purpose of Regulatory Directive DIR98-05, *Chemical Pesticides Research Permit Guideline* (http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir9805-e.pdf), published in May 1998, is to inform registrants, researchers and other interested groups of procedures that do not affect data requirements, to reflect current practices of the PMRA.



Requirements for research involving pheromones and other semiochemicals, or microbial pest control agents are outlined in *Guidelines for the Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals* (http://www.hc-sc.gc.ca/pmra-arla/english/pdf/pro/pro2002-02-e.pdf) and *Guidelines for the Registration of Microbial Pest Control Agents and Products*, (http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir2001-02-e.pdf), respectively.

Prior Informed Consent

Canada was one of 140 countries that participated in the negotiation of the Rotterdam Convention on Prior Informed Consent (PIC) procedures in 1998, and acceded to the Convention in August 2002. The Convention is based on a similar voluntary procedure that has been in place since 1989 and will come into force once 50 countries have ratified it.

The Convention covers 22 pesticides, five industrial chemicals and five severely hazardous pesticide formulations that are banned or severely restricted by at least two Parties. These chemicals may not be exported without prior government consent from the importing country. The Convention also promotes their safe use through labelling standards, technical assistance, and other forms of support.

The Export of Substances Under the Rotterdam Convention Regulations under the *Canadian Environmental Protection Act* 1999 were developed cooperatively by Environment Canada and PMRA to implement the PIC procedures in Canada, and came into force in December 2002. These Regulations allow export of listed chemicals only when the importing country has provided its consent through the PIC procedure, or when the exporter has obtained written consent from the importing country. Exporters are required to obtain a permit each year for each chemical and country of destination.

In addition to complying with the Regulations, the PMRA actively participates in the Convention by acting as the Designated National Authority for pesticides and as the Canadian member of the Interim Chemical Review Committee. The Committee provides technical advice to the decision making body of the Convention, the International Negotiating Committee.

PMRA ARLA

Pest Management Regulatory Agency Progress Rep 2003

1998–2003 Progress Report

PROMOTING SUSTAINABLE PEST MANAGEMENT

SUSTAINABLE PEST MANAGEMENT AND INTEGRATED PEST MANAGEMENT

The PMRA continues to work towards sustainable pest management. The goals of sustainable pest management are:

- to meet society's needs for human health protection, food and fibre production and the effective use of resources;
- to conserve or enhance natural resources and the quality of the environment for future generations; and
- to be economically viable.

The PMRA's main contribution to sustainable pest management is pesticide risk reduction. In its May 2000 report, *Pesticides: Making the Right Choice for the Protection of Health and the Environment*, the Standing Committee on Environment and Sustainable Development recommended that the PMRA develop a pesticide *use* reduction policy. However, reduction in the quantity of pesticides used does not necessarily lead to proportionate reduction in *risk*, because pesticides differ significantly in their potency. For this reason, the PMRA supports a broader risk reduction approach that ultimately leads to better health and environmental protection and can encompass use reduction as appropriate.

The October 2000 Government Response to the Standing Committee Report outlined an approach to pesticide risk reduction supported by four pillars:

- reduced-risk associated with pest control products;
- reduced reliance on pest control products as the sole means of pest control;
- research, monitoring and reporting on risk; and
- public communication, consultation and education.

Achievement of pesticide risk reduction requires working with partners at the federal and provincial/territorial level and with stakeholders, incorporating the concepts of Integrated Pest Management (IPM) and Integrated Crop Management (ICM).

IPM is an important component of sustainable pest management. IPM programs:

- manage crops to prevent pests from becoming a threat (by crop rotation, for example);
- identify potential pests (weeds, diseases, insects, etc.);
- monitor environmental conditions, pest and beneficial organism populations, and pest damage;
- decide whether treatment is needed on the basis of populations and damage thresholds;

- use biological, mechanical and behavioural control methods (such as resistant crop varieties, physical barriers and traps) to reduce pest populations to acceptable levels;
- when necessary, use targeted applications of pesticides; and
- have a built-in evaluation process.

IPM extends far beyond products, whether chemical or alternative, and can include a wide variety of prevention and treatment techniques. The tools and techniques used in an IPM program, and the costs and benefits of each, are specific to particular crops or pests. IPM reduces reliance on pesticides as the sole approach to pest management. By ensuring that pesticide applications are warranted, well-timed and performed in concert with other management practices, IPM can reduce possible adverse heath or environmental effects. It can also extend the useful life span of a pesticide by delaying the development of resistance.

A key IPM concept is that it is necessary to take action against pests only when their numbers warrant, not as a routine measure. In most cases it is only necessary to suppress pest populations, not eliminate them. In an IPM program, pest managers use regular inspections to determine whether action is necessary. If treatment is warranted, pest managers choose the most appropriate combination of control measures for the site.

The regulatory system also endeavours to optimize the use of conventional chemical pest control products by amending the rate, timing or method of application to reduce adverse impacts on naturally occurring beneficial organisms. To retain pesticides with a critical role in an IPM program, mechanisms to mitigate risks to humans and non-target organisms may be considered, such as applicator certification, buffer zones, or advanced application equipment. In addition, it is essential to maintain an active re-evaluation program to ensure that pesticides that remain on the market meet current standards.

Commodity-based IPM Projects

The PMRA coordinates the development of voluntary, national risk reduction strategies in cooperation with its partners, including grower organizations, manufacturers, other federal government departments, provinces, research establishments as well as non-government health, environment and consumer organizations.

The PMRA and AAFC are finalizing a risk reduction strategy for pest management in agriculture that is the basis for commodity-specific risk reduction programs. The Agency is also working with other partners to develop risk reduction strategies for pest management in other sectors such as forestry.

IPM Partnership Projects

The PMRA has undertaken a series of IPM Partnership Projects in the past with grower organizations, other federal departments, provincial governments, and stakeholders.

The PMRA is participating in or has participated in the following IPM partnership programs.

Integrated Management Alternatives to Methyl Bromide in the Food Processing Sector

This industry is faced with the phase out of methyl bromide by 1 January 2005 as agreed under the Montreal Protocol. During the last 10 years, the PMRA has participated in working groups with stakeholders, including the milling industry and other federal departments, to identify alternatives to methyl bromide. A number of options have been explored, and several promising treatments are being tested.

Integrated Fruit Management for a Sustainable Production (IFP)

Through the Apple IFP Steering Committee, the PMRA worked to develop a set of IFP guidelines. A first version was finalized in April 2002. A pilot project based on these guidelines was initiated in 2002.

A two-day IFP workshop was organized for growers and marketers in February 2003, to learn from other IFP programs and to establish a context for the Canadian IFP program. The IFP Steering Committee determined that they would need to develop educational material and training resources for producers and also to plan their communication strategy for effective marketing of the fruit produced under the IFP program.

Integrated Pest Management in Canola (NAFTA)

A risk reduction plan for canola was developed by joint efforts of the Canola Council of Canada, the PMRA and other stakeholders. The strategy encouraged growers to use environmentally sound approaches for the production of canola. This contributed to the healthy image that is now used around the world to market this Canadian oil product. The completion of the strategy is expected in 2004, with the creation of an on-line, electronic IPM decision-making system for canola growers.

Integrated Management of Sea Lice in Salmon Aquaculture

A number of stakeholders collaborated with the PMRA on the problem of sea lice in salmon aquaculture. The project was completed in 2003 with the publication of two IPM documents. An overview of the project is found at http://www.hc-sc.gc.ca/pmra-arla/english/pdf/spm/spm2003-e.pdf and a fact sheet relating to the use of integrated pest management of sea lice in aquaculture is located at http://www.hc-sc.gc.ca/pmra-arla/english/pdf/fact/fs_ipmsealice-e.pdf.

Integrated Management of Late Blight and Colorado Potato Beetle (NAFTA)

PMRA worked with stakeholders to address the problems of late Blight and Colorado Potato Beetle. These early programs were concluded in 1997 through the development and publication of two IPM documents. A document on the use of IPM to control late blight on potatoes is found at http://www.hc-sc.gc.ca/pmra-arla/english/pdf/spm/spm_s9601-e.pdf, and the corresponding fact sheet is located at http://www.hc-sc.gc.ca/pmra-arla/english/pdf/spm/spm_s9602-e.pdf.

National Strategy for Sustainable Pest Management of Spruce Budworm in Forestry

The PMRA collaborated with a number of stakeholders to identify and develop a publication regarding IPM practices used by the industry to combat this significant forest pest. This publication will be available in 2004.

Integrated Pest Management in Cranberry Production

The Eastern Region Cranberry IPM Manual will be finalized in 2004. Following in the steps of a similar success in western Canada, this manual is the result of a concerted five year effort to provide growers in eastern Canada and the U.S. with practical guidance on implementing a sustainable integrated approach to cranberry production. The process began at a meeting in Montreal in 1998, when growers, provincial specialists, researchers and pesticide manufacturers recognized the need for sustainable production practices in cranberry production. Funding was obtained to create the IPM manual from provincial governments and grower organizations in both Canada and the U.S. Because both Canadian and American cranberry growers would benefit from this manual, this initiative was formally recognized as a NAFTA project in June 1998.

Commodity-based Initiatives

Jointly facilitated by AAFC and the PMRA, several commodity-based strategic plans have recently been initiated.

Integrated Pest Management for the Potato Industry in PEI and New Brunswick

To address some of the challenges facing this commodity, the PMRA participated in a stakeholder meeting in February 2003; the report from this meeting will be published in 2004. A strategy is being developed by a steering committee of stakeholders, including growers, processors, the pesticide industry, non-governmental organizations and government officials.

Integrated Crop Management for the Pulse Industry

A stakeholder meeting was held in July 2002, and a second meeting followed in February 2003 to identify pest problems, trade irritants and the loss of existing pesticides products. Priorities range from short-term research to the need for the registration of reduced-risk products and outreach activities to facilitate the adoption of the new tools by the growers. A risk reduction strategy is currently being developed.

Richardson's Ground Squirrel Control

This project will address the need for the control of Richardson's Ground Squirrels, including the identification of reliable alternatives to strychnine. A steering committee including the producers, the pesticide industry, provincial officials, the PMRA, AAFC and researchers has been established to lead the development of a risk reduction strategy.

National Strategy for Sustainable Pest Management in Urban Landscapes

The FPT Action Plan on Urban Use Pesticides (http://www.hc-sc.gc.ca/pmra-arla/english/pdf/hlawns/hl-ActionPlan-e.pdf) was announced in October 2000, to help Canadians reduce their reliance on pesticides in the urban setting. Focussing on outdoor use of pesticides, the Action Plan identified three key elements: the Healthy Lawns Strategy for Urban Pesticide Risk Reduction, Registration of New Reduced-risk Products and Product Re-evaluation.

1. Under the first element of the Action Plan, the Healthy Lawns Strategy for Urban Pesticide Risk Reduction, the PMRA, the provinces and the territories are helping Canadians to minimize the risks associated with pesticides for lawn care by emphasizing pest prevention, use of reduced-risk products and application of pesticides only when necessary.

   In February 2002, the PMRA, the provinces and the territories completed a public consultation on their *Proposal for a Harmonized Pesticide Classification System for Canada* (http://www.hc-sc.gc.ca/pmra-arla/english/pdf/fpt/ciwg/propdoc-e.pdf). Under the proposal, domestic class pesticides would be placed in one of two categories to separate the lower- and the higher-risk products. The proposed system would require vendors of higher-risk domestic class pesticides to employ one or more trained/certified persons to ensure that purchasers of these products are provided with appropriate pest control advice and product information. Comments on the proposal are presently being analyzed. Implementation of the proposed classification system would ultimately result in improved training of vendors of higher-risk domestic class pesticides and more controlled use of these products.

   In March 2002, a working group of the PMRA, the provinces and stakeholders assessed whether specific types of lawncare products should be available to homeowners. This assessment determined that domestic class fungicide/insecticide combinations have very limited IPM compatibility and that domestic class herbicide/fertilizer combinations ("weed n' feed" products) are prone to improper use. To address these concerns, voluntary discontinuation of domestic class fungicide/insecticide combinations has been proposed. As well, manufacturers of herbicide/fertilizer combinations have been asked to follow up on their commitment to provide tear-off advisories to vendors for placement in close proximity to product displays. The PMRA will explore additional means of addressing concerns about fertilizer/herbicide products in conjunction with the CFIA in 2003.

   In December 2002, the PMRA, the provinces and stakeholders developed recommendations for improving risk reduction information on labels, including simplification of label statements required under the PCPA regulations, development of a policy for child resistant packaging on domestic class products and development of a poster/fact sheet to educate consumers on the importance of reading product labels. The meeting report has been finalized and the PMRA is developing a plan for implementation of the highest priority recommendations. Implementation of the recommendations will serve to make product labelling/packaging compatible with enhanced risk reduction practices.

Through the FPT Working Group on Pesticide Education, Training and Certification, enhanced IPM training for pesticide applicators is being developed . The Landscape Module of the Standard for Pesticide Education, Training and Certification is being revised to include IPM concepts for landscape pests. Once finalized, these improvements will enhance the training of lawn care/ landscape service providers and green space managers.

The PMRA and the provinces have developed training materials and programs to educate homeowners on healthy lawn practices that minimize the need for pesticides. Groups, government agencies, communities and individuals have been encouraged to make use of key messages posted on the Healthy Lawns website to promote homeowner adoption of IPM approaches. An article highlighting good spring-time lawn maintenance practices that will reduce the need for pesticides has been disseminated to large, small and community newspapers across the country, and development of complementing summer and fall articles is underway. Copies of the PMRA's *Healthy Lawn Tips* (http://www.healthylawns.ca/english/html/hg-e_flash.shtml#flash) folder have been distributed to PMRA regional offices, provincial governments and members of the Federation of Canadian Municipalities to encourage homeowner education on practices which minimize the need for lawncare pesticides.

As a result of these initiatives, several municipalities have used the key messages on their websites, while other municipalities and federal departments have ordered copies of the *Healthy Lawn Tips* folder.

Links to credible sources of information on healthy lawn practices for homeowners, lawn and landscape service providers, municipal parks managers, golf course managers and grounds keepers of school playing fields are added to the Healthy Lawns website (www.healthylawns.net) on an ongoing basis.

2. The second element under the Action Plan is registration of new reduced-risk products. The May 2002 PMRA initiative to extend the Reduced-risk Joint Review program that has been underway with the USEPA is described on pages 18–20 of this report, while the progress in registering reduced-risk pesticides is outlined on page 48.

3. The third element of the Action Plan is the priority re-evaluation of the most common chemicals in lawn care pesticides. The intent of these re-evaluations is to apply the most modern risk assessment principles, including additional safety factors to protect children, to products used in the urban setting. A re-evaluation involves a comprehensive review of the scientific data available on the pesticide to determine whether it meets modern safety standards.

The PMRA's re-evaluations of chlorpyrifos, diazinon and malathion are complete. These products have been, or are being discontinued for use in turf. Reviews for 2,4-D, dicamba, MCPA, mecoprop and carbaryl are in the final stages. Additional exposure data from the Outdoor Residential Task Force was submitted in the Spring 2003, and is being considered before these assessments are finalized.

Pesticide Sales Data Base

Canada has recognized that, in order to regulate pest control products appropriately and efficiently, there is a need for comprehensive information about the extent to which they are used. Such information is not only essential to follow trends of pesticide use over time and to track the effectiveness of risk reduction efforts, but it would also contribute to the ability of the PMRA and the provinces/territories to set priorities and to assess and mitigate health and environmental risks during new product evaluation as well as re-evaluation and special review of older pesticides.

Internationally, member countries of the OECD agree on the importance of data on pesticide use, but also recognize that the collection of use data is expensive. As a result, most OECD-member countries collect sales data as a reasonable surrogate for use information. Once in force, the new PCPA will require all registrants, as a condition of registration, to record, retain and report to the Minister information on sales of their products in the form and manner directed by the Minister and in accordance with regulations.

A FPT Committee was initiated in 1997 with the goal of developing an approach to collecting annual sales data (in kilograms) for all pesticide products from all registrants by province/territory. The Working Group includes representation from the PMRA, provinces and territories, the pesticide and agriculture industries as well as environmental and consumer organizations. Registrants belonging to the national pesticide industry associations voluntarily contributed sales data for the years 1999 and 2000, thereby enabling the PMRA to test components of a National Pesticide Sales Data Base including an electronic data entry system, the database structure and reporting functions.

EVALUATING SUBMISSIONS

NEW SUBMISSIONS

Before a pesticide is considered for registration in Canada, it must undergo extensive testing to identify potential risks to human health and the environment, as well as to demonstrate its value. The manufacturer must carry out the necessary scientific tests and studies before submitting data and results to the PMRA. The PMRA carefully reviews this information to determine if the product is acceptable for use in Canada. The Agency's decision to register or deny registration is based on an objective scientific assessment, using stringent scientific standards that are consistent with approaches used in other OECD-member countries.

The health, environmental and value assessments carried out by PMRA evaluators address:

- Where, how and by whom will the pest control product be used?
- What is its toxicity?
- Are there any potential health hazards to users or bystanders?
- Will our food and drinking water be affected?
- What is the impact on the terrestrial and aquatic environment?
- Is the product persistent?
- What is the value of the products? Assessing value helps establish the lowest effective rate for pesticide application. The less pesticide used, the less risk posed to health and the environment.

In 1996, the PMRA introduced a new approach to managing submissions, along with performance standards. Fundamental to the new approach was that applicants would provide complete, good quality submissions and that the PMRA would conduct its review of these complete submissions within the stated performance standards. The responsibilities, time lines and performance standards were outlined in the *Management of Submissions Policy* (MOSP) (http://www.hc-sc.gc.ca/pmra-arla/english/pdf/pro/pro9601-e.pdf) on 7 June 1996. Submissions were classified into a number of categories, as follows.

Category A submissions include new active ingredients and their companion end-use product(s), as well as major new uses, or submissions to establish an MRL for a new active ingredient. User Requested Minor Use Registrations (URMURs) and joint reviews are also included in this category.

Category B submissions include submissions for new uses or new formulations.

Category C submissions are submissions that are based on previously established precedents or that have reduced data requirements.

Category D includes submissions to register or to amend products within particular programs, for example, Import for Manufacture and Export Program, Own Use Import, Master Copy, Private Label, User Requested Minor Use Label Expansion (URMULE), and Renewals.

Category E includes submissions for research permits and research notifications carried out in Canada.

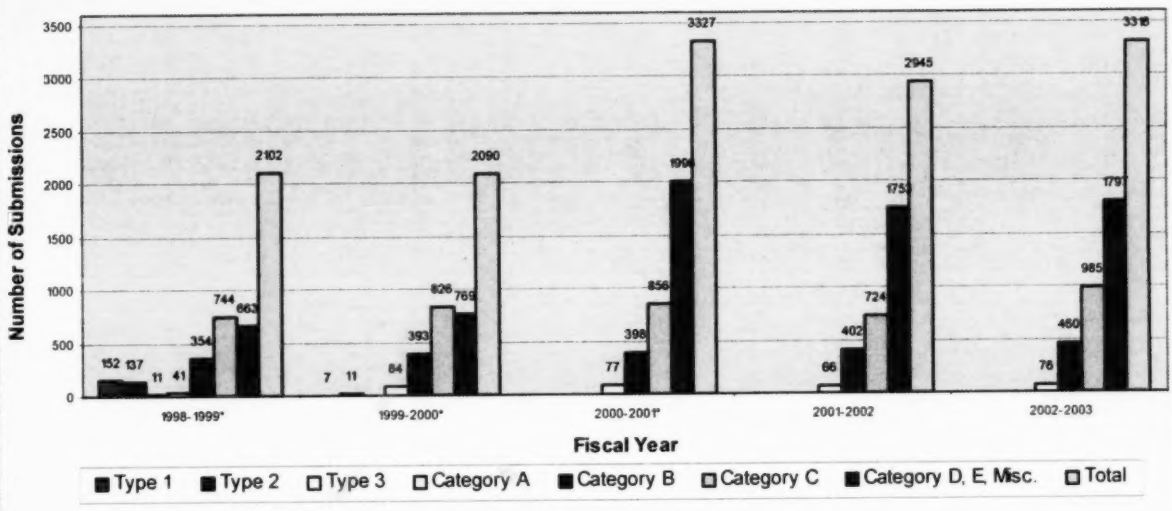
PMRA Workload—New Submissions

During the past five years, PMRA received 2800 submissions on average, with a higher number (approximately 3300) during the last three years. Category A and B submissions accounted for about 16% of the total.

Chart 1 provides information concerning the number of submissions that were completed by the PMRA for the period 1 April 1998 to 31 March 2003. Completed submissions may be registered, withdrawn (generally requested by applicant) or rejected (a PMRA decision based on unacceptable risk or an incomplete database).

When the PMRA was formed, a large number of submissions were being reviewed. Completion of these "in-progress" submissions was a major undertaking during the early years of the PMRA. Some of the in-progress submissions that were in the very early stages of review were re-categorized into the applicable category (A or B) to facilitate the tracking of these submissions. However, since they were received prior to the MOSP, they were not screened for completeness, and applicants were given additional time to complete their submissions. As a result, considerable time was required to complete many of these submissions. These submissions were categorized into three "types" (1, 2 or 3).

Chart 1: Number of submissions that were completed# by the PMRA for the period 1 April 1998 to 31 March 2003



Completed included Registered, Withdrawn and Rejected
* Does not include URM ULE submissions
Submission types are explained in the preceding paragraph.
Submission categories are explained on pages 37 and 38.

For the PMRA to meet the performance standard defined in the MOSP for a given category of submissions, 90% of the submissions in that category must be completed within the stated review time. The PMRA's success in meeting performance standards for standard Category A submissions is provided in Table 1. Information on Category A submissions is provided as these submissions are for new products and are often of the greatest interest to stakeholders.

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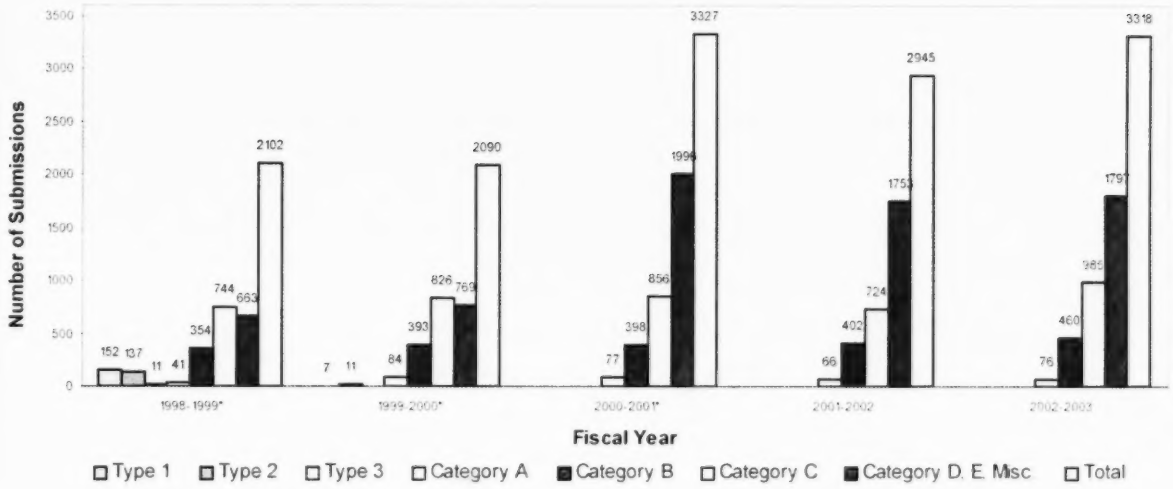

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Table 1 Completed[1] Standard Category A Submissions Subject to the MOSP (Excluding Deviations)

	Submissions Screened and Review Completed[1]	% Meeting Review Performance Standard[2]
April 1998 March 1999	13	13 13 (100%)
April 1999 March 2000	35	33 35 (94%)[3] 24 35 (69%)[3]
April 2000 March 2001	42	36 42 (86%)
April 2001 March 2002	31	29 31 (94%)
April 2002 March 2003	34	25 34 (74%)

Notes: [1] Completed means registered, granted, approved, rejected, withdrawn.
[2] 18 months (550 days) for a quality submission
[3] Eleven submissions had a review time ranging from 552 to 566 days, i.e., 2 to 16 days over the performance standard of 550 days. These eleven submissions had incorrect deadline dates related to the change over in databases. On nine of these submissions the deadlines in the database were met.

Total Time to Registration

The amount of time following the receipt of a pesticide submission that is required to reach a final decision on that submission is known as the total time to registration, and is a measure of both PMRA and applicant performance.

Figure 1 shows the average total time to registration (or life cycle) for standard Category A submissions, for each of the five years from 1 April 1998 to 31 March 2003. The component parts of the life cycle are also shown, i.e., average time for the PMRA to complete its steps (PMRA time), average time for applicants to address deficiencies (applicant time), average time for the PMRA to review information related to deficiencies in a submission (deficiency time) and average public consultation time.

PMRA time consists of a verification step, a first screen, a preliminary review step, an evaluation step, the first decision and Proposed Regulatory Decision Document (PRDD) preparation, decision time after public consultation, and the first final label review.

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	[illegible]	% Meeting Review Performance Standard[2]
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PMRA time consists of a verification step, a first screen, a preliminary review step, an evaluation step, the first decision and Proposed Regulatory Decision Document (PRDD) preparation, decision time after public consultation, and the first final label review.

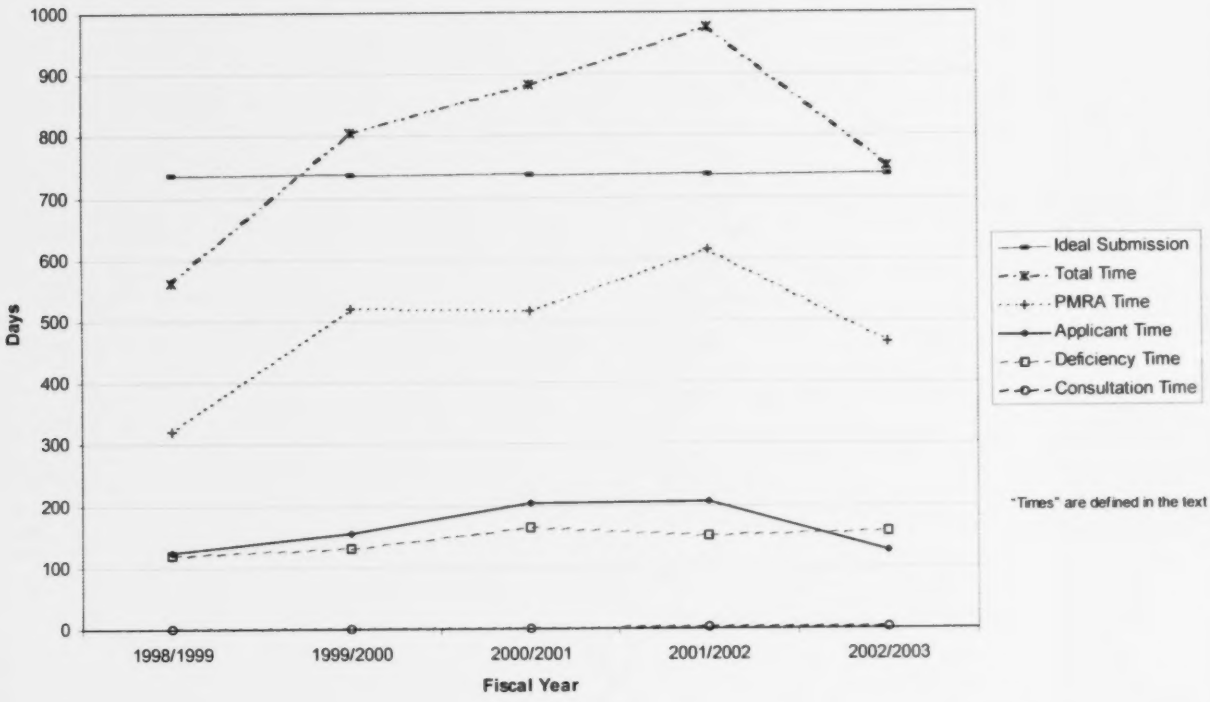
Applicant time includes all time that a submission is waiting for action by the applicant to respond to screening deficiencies, preliminary review deficiencies, evaluation deficiencies, final label deficiencies, missing fees, and the submission of final printed labels.

Deficiency time includes any extra cycles resulting from submission deficiencies, including additional screens, further preliminary review, additional review as well as decision times resulting from evaluation deficiencies and additional final label reviews.

Public consultation time is the 45 day period for public comment on a PRDD.

If submissions were "ideal"—that is, complete and had no deficiencies—and the PMRA met performance standards, the total time to registration would be the sum of the PMRA time and public consultation time. Figure 1 includes the projected time of an ideal submission.

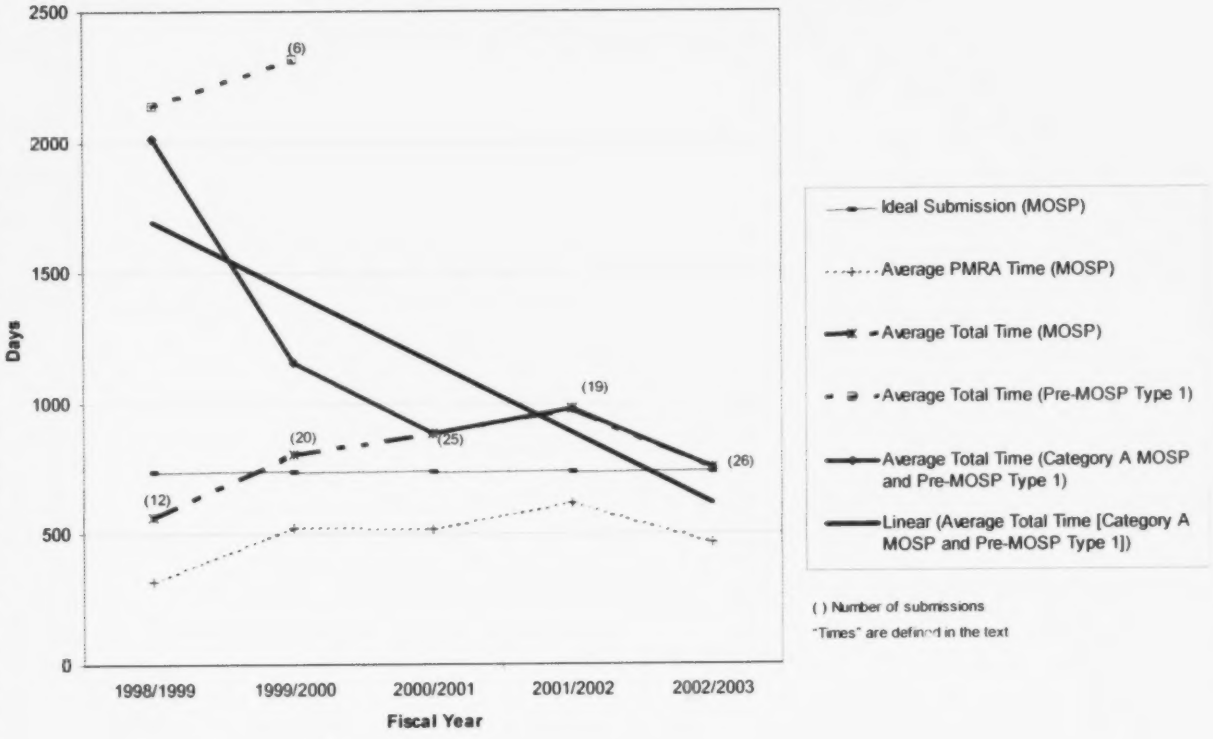
Figure 1: Registered Standard Category A Submissions Subject to the MOSP – Average Times (Including Deviations)

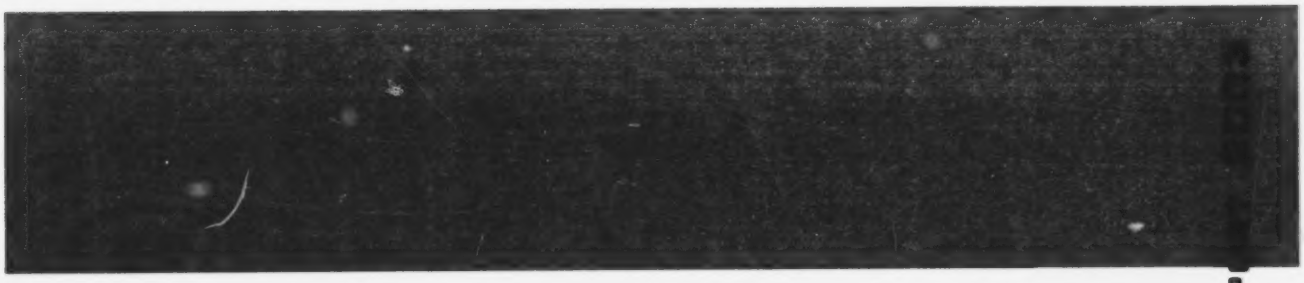


The average PMRA time and average public consultation times for Category A submissions from 1998–1999 to 2002–2003 has been shorter than the expected 737 days for an ideal standard Category A submission. Had the submissions been complete, average times to registration would have been much shorter. Unfortunately, over the five year period, only two out of seventy-five submissions met the criteria for an ideal submission. Nevertheless, gains on reducing the total time to registration continue to be made and collective efforts are being made to further reduce these time lines.

The introduction of the MOSP has contributed to a reduction in the time to registration. Figure 2 illustrates the total time to registration for each of the fiscal years from 1 April 1998 to 31 March 2003 for standard category A submissions subject to the MOSP as well as for the Type 1 in-progress (pre-MOSP) submissions that were similar to Category A submissions.

Figure 2: Registered Standard Category A and Type 1 Submissions – Average Times (Deviations Included)





In 1998–1999, Type 1 in-progress submissions dominated the registrations (136 vs 12), and the average time to registration was 2013 days. By 1999-2000, the MOSP standard Category A submissions predominated, and the average total time to registration started to decrease. In 2002–2003, the average total time to registration for standard Category A submissions dropped to 751 days, which means that products are registered, on average, 168% faster than five years ago.

Joint Review

The *Joint Review Pilot Program for Reduced-Risk Chemicals*, announced in March 1996, is a crucial part of the ground-breaking international harmonization of pesticide regulations between Canada, the U.S. and Mexico under NAFTA.

Lessons learned during these early reviews led to a revised process in 1998, described in *NAFTA Technical Working Group on Pesticides Revised Procedures for Joint Review* (http://www.hc-sc.gc.ca/pmra-arla/english/pdf/nafta/naftajr/nafta-jr-pest-e.pdf).

In 1999, the joint review process was expanded to include organophosphate replacements, with an 18-month review time. A further revision in 2002 added another category of joint review (a category for submissions that did not meet any of the other criteria, with negotiated timelines). Procedures under the Joint Review process for microbial pesticides or arthropod semiochemicals (including pheromones) were updated several times. Recently, timelines for pheromones that are jointly reviewed were reduced to six months and a publication, *Procedures for Joint Review of Microbials and Semiochemicals* (http://www.hc-sc.gc.ca/pmra-arla/english/pdf/nafta/naftajr/nafta_jr_micro-e.pdf), was issued.

In addition to joint reviews, a work sharing program improves the efficiency of the review process. Under work sharing, the Agency uses the completed reviews from other countries to expedite its analysis. Regular reports of joint review activity are published on the PMRA website (http://www.hc-sc.gc.ca/pmra-arla/english/pubs/jnt_rev-e.html)

As of 31 March 2003, 35 registrations have been granted under the Joint Review/Workshare Programs, plus 1 minor use label expansion and one import MRL. This includes 11 traditional chemicals, 18 reduced-risk chemicals, 4 microbials and 2 pheromones (active ingredients and end-use products). There are 21 submissions undergoing joint reviews or workshare reviews, of which 12 are traditional chemicals, five are reduced-risk products and four are microbials.

Of the joint review submissions that have been completed since the program began, 66% met the USEPA/PMRA joint performance standards. However, of the 34%, or 11 submissions, that did not meet the standard, the additional time required ranged from 1 to 51 days.

SOME HIGHLIGHTS OF JOINT REVIEW ACTIVITY

- The first reduced-risk chemical was approved through the Joint Review process in May, 1998. Simultaneous registration gave Canadian and U.S. fruit growers equal access to the fungicide Cyprodinil (Vangard®), an advanced, safer product for use on apples.

- The first jointly-reviewed herbicide received simultaneous, time-limited registrations from the PMRA and the USEPA in time for the 1999 growing season. The rates, timing and frequency of application for diflufenzopyr (Distinct®) are the same in both countries, providing greater fairness to growers, and the harmonized maximum residue limits avoid trade irritants.

- For the first time, a chemical was reviewed through international cooperation extending beyond the NAFTA TWG. A pilot project resulted in the PMRA registering sulfosulfuron (Sundance®), a herbicide for the control of wild oats and certain broadleaf weeds in wheat. The effort included Canada, the United States, Australia and the EU, with Ireland as lead EU country.

- In 1999, the PMRA received its first application for a joint review of Zoxamide by all three NAFTA partners—Canada, the United States, and Mexico. This application was submitted in the universal OECD format, a direct result of OECD harmonization efforts.

- 1999–2000 saw the registration of fenhexamid technical grade active ingredient, and Elevate® 50 WDG fungicide for use on grapes, strawberries and ornamentals through the joint review process.

- Acetamiprid was registered jointly in Canada and the U.S. in 2002. This registration decision provided access in Canada to a large number of new uses, including not only oilseeds but also many horticultural crops.

The Minor Use Initiative

'Minor use' pesticide products are those used in such small quantities that manufacturers find the sales potential is not sufficient to seek a registration in Canada. Therefore, such products may not be available here. Many of these products are regarded as essential to cost-effective pest control and the competitiveness and sustainability of agriculture, forestry, aquaculture and other sectors.

Improving the availability of minor use pesticides has been one of the priorities for the Agency. Major changes have occurred to encourage availability of these important products to Canadian producers of specialty crops. In May 2002, the PMRA doubled the resources for review of minor use pesticides, while in June 2002, the government allocated $54.5 million over six years to AAFC and the PMRA, to give Canadian producers better access to minor use and reduced-risk pesticides.

The lack of data that would permit the registration of pesticides for minor uses has been a significant problem in Canada. With the government announcement, AAFC will build a close alliance with the Minor Use IR-4 project in the U.S., to maximize efficiencies in field trials and laboratory residue testing. Joint work with the IR-4 project and the NAFTA TWG will build towards the goal of a North American pesticide market and the minimization of trade irritants.

In May 2002, the Ministers of Health and Agriculture and Agri-Food announced that a full-time Minor Use Advisor (Ombudsperson) would be appointed in PMRA, with the position modelled after that of the Minor Use Advisor of the USEPA.

Over the past eleven months, stakeholders, provincial officials and AAFC and the PMRA have established a national needs list consisting of 1800 projects that growers have identified as solutions for their pesticide requirements. A group of 90 growers, and 50 scientists and crop specialists met in Ottawa in March 2003 to identify 35 projects from this list that would receive funding from AAFC in 2003.

The PMRA has three programs that lead to registration of products for minor uses.

The User Requested Minor Use Label Expansion (URMULE) program (http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir2001-01-e.pdf) has existed since the late 1970s. As the name suggests, this program was based on adding minor uses to products that were currently registered in Canada. The URMULE program considers the expansion of a label for a new minor use of a product, whether chemical, microbial or pheromone, that has both an active ingredient and an end-use product currently registered in Canada. The use expansion will be considered only if the product is efficacious and the risks are acceptable. The Agency now publishes regular updates of URMULE registrations to inform interested parties. These updates can be found at http://www.hc-sc.gc.ca/pmra-arla/english/pubs/urmule-e.html.

In 1999, a new program for the registration of pesticides based on active ingredients that are not currently available in Canada, but were recently registered in the United States, European Union, or by another reliable foreign regulator, was established. This program is known as the User Requested Minor Use Registration (URMUR). The purpose of the program is to encourage the registration of products, including biopesticides such as microbials and pheromones, that are registered in the U.S. or other OECD-member countries, but have not been pursued here due to potential low volume of sales. The initial registration must not be older than five years, the reviews must be included in the submission and the timeline for review of a complete submission is 12 months. The directive is located at http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir9905-e.pdf.

Key to the availability of products for minor uses is submissions for new active ingredients that are developed to allow for the approval of both major and minor uses. In addition to the two formal programs for minor use, PMRA is also continuing to encourage registrants to participate in joint reviews, through which a registrant can obtain registration at the same time in both Canada and the U.S. This process usually leads to pesticide submissions that seek approval for many more uses of the pesticide in Canada. Many of these uses are for minor crops. PMRA is also encouraging registrants who are seeking registration only in Canada to include as many uses (including minor uses) as possible in their initial submission, thereby facilitating earlier availability of products for minor uses. If these products are considered to be reduced-risk products, they will be eligible for the new PMRA Initiative for Reduced-Risk Pesticides, that was introduced in May 2002. Under this initiative, the USEPA criteria and designation of reduced risk are accepted and the review of submissions that meet the reduced-risk definition are expedited.
New minor uses registered under the URMULE program for the period 1 April 2000 to 31 March 2003

are as follows: 2000–2001, 82 new uses were registered. This number rose to 137 in 2001–2002, and to 314 in 2002–2003. New minor uses registered under the Registrant sponsored submissions have increased from 48 in 2000–2001 to 429 in 2002–2003.

	2000–2001	2001–2002	2002–2003
URMULE	82	137	314
Registrant Sponsored Submissions	48	35	429

Reduced-risk Products

Earlier in this report, products that are considered to be reduced risk have been described, along with the PMRA initiatives to increase the submission of such products for registration.

The number of reduced-risk pesticides has risen dramatically over the eight years since the beginning of the PMRA. Forty-four reduced-risk active ingredients (biopesticides and reduced-risk chemicals) have been registered since 1995, compared with 11 active ingredients that were registered over the previous 11 years. At this time, 74% of the chemical active ingredients designated as reduced risk in the U.S. are now either registered or pending in Canada.

The following histogram shows the distribution of reduced-risk active ingredients registered over the last 20 years.

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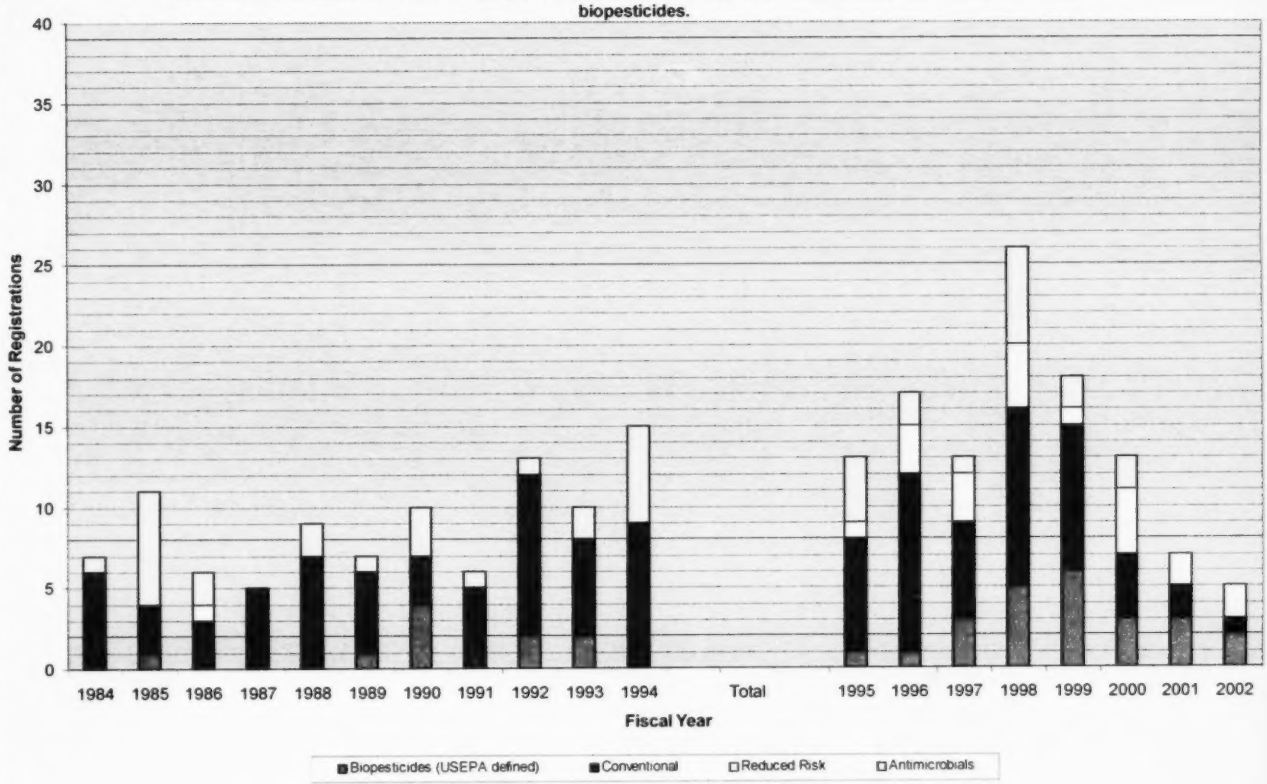
The following histogram shows the distribution of reduced-risk active ingredients registered over the last 20 years.

CHART 2: Number of Actives Registered by Category

New Active Registrations Only from Date of First Registration

NOTE: Chart includes antimicrobials. Biopesticides (USEPA defined) includes microbials, pheromones and "other" biopesticides.



Pest Management Regulatory Agency Progress Report 2003

RE-EVALUATING PEST CONTROL PRODUCTS

RE-EVALUATION OF PESTICIDE ACTIVE INGREDIENTS IN CANADA

Today, close to 550 pesticide active ingredients are in more than 7000 products that are registered under the PCPA for use in Canada. At the time of their registration, these pesticides were considered acceptable on the basis of an assessment of their safety, merit and value. However, the scientific knowledge that forms the underpinning of these assessments is continually evolving and new methodologies and tools are being integrated into regulatory risk assessments. Also, the re-evaluation of older pesticides can take into consideration the full extent of the use patterns of the active ingredients, the diversity of their end-use products, and their market penetration. These parameters would not have been fully apparent at the time of initial registration. For these reasons, the PMRA has developed a re-evaluation program that uses current scientific approaches to examine the continued acceptability of older active ingredients and their end-use products. These modern risk assessment approaches include application of additional safety factors for the protection of children, consideration of aggregate exposure from combined dietary, residential and drinking water exposure as well as cumulative risk for chemicals considered to exhibit a common mechanism of toxicity. New methodologies and science policy documents have been developed by the PMRA scientists to equip the agency with the tools to conduct the most advanced and modern risk assessments.

The PMRA's re-evaluation program is described in the *PMRA Re-evaluation Program* (http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir2001-03-e.pdf). The new approach to re-evaluation, recommended by stakeholders and supported by PMAC, is to build on available foreign reviews and expand the extensive work-sharing arrangements with the USEPA. This internationally harmonized approach will increase regulatory efficiency and help to maintain a level Canada-U.S. playing field for trade in agricultural and other products treated with pesticides.

The goal of the program is to re-evaluate all products registered on or before 31 December 1994. Of the 550 currently registered pesticide active ingredients and their end-use products on the market in Canada, 405 require re-evaluation. The strong reliance of the Canadian re-evaluation program on the availability of U.S. reviews ties the completion of the Canadian program to that of the U.S. program. The PMRA aims to complete re-evaluation of the 405 Canadian active ingredients within the same time frame as the USEPA.

STATUS OF RE-EVALUATION

As of 31 March 2003, 61 active ingredients have been addressed through the current re-evaluation program. Publications providing details of 53 of these pesticides are available on the PMRA website, http://www.hc-sc.gc.ca/pmra-arla.

- Of the 53 active ingredients addressed in publications, six active ingredients and some uses of their end-use products have been approved or proposed for continuing registration, with updated labels that reflect mitigation measures needed for safe use.

- Of the remaining active ingredients that have been fully addressed, 33 have been discontinued by the registrants and 14 have been phased out because of environmental or health assessments.

Some of the highlights of the re-evaluation program are listed below.

- A re-evaluation of the insect repellent DEET was completed, resulting in new use standards and labelling (e.g., products restricted to 30% or less DEET). Two additional insect repellents (MGK Synergist 264 and MGK repellent 326) were voluntarily discontinued and have been phased out.

- Consultation documents describing the results of the health and environmental assessments for seven organophosphate insecticides have been published. Three of these organophosphate compounds are proposed for phase out while the remaining four are proposed for continued registration with mitigation measures reflecting the modern risk assessment. An additional five organophosphate active ingredients have been discontinued by registrants as a result of the PMRA re-evaluation program.

- Residential and turf uses for two major organophosphate insecticides (chlorpyrifos and diazinon) have been phased out.

- Domestic class products for naled, dimethoate and phosmet are being phased out.

- A modern safety assessment of malathion use in mosquito abatement programs, has been conducted in anticipation of control programs for mosquitos as potential carriers of West Nile virus. The re-evaluation assessed modern data and applied stringent safety factors for the protection of children.

- A special review of tributyl tin antifouling paints has been completed resulting in the phase out of these uses on the basis of environmental concerns as of 31 October 2002. This phase out is consistent with the resolution adopted by the Marine Environmental Protection Committee of the International Maritime Organization to develop a legally binding global Convention to address the harmful effects of antifouling paints.

- A special review of lindane seed treatments was completed in 2002, resulting in voluntary discontinuation of sale by some registrants (31 December 2004) and suspension of registration for others. Other above ground agricultural uses of lindane had already been phased out as result of a previous action, resulting in the end of lindane uses as a pest control product in Canada.

The PMRA is actively cooperating with the USEPA in the re-evaluation of the three heavy duty wood preservatives (CCA, creosote and pentachlorophenol). It is expected that these assessments will be complete in 2004 and will be the most rigorous assessments ever conducted of these three active ingredients. In the interim the following measures have been taken.

- Environment Canada and Health Canada have cooperated with the CCA wood treatment industry to develop a comprehensive labelling and bilingual public information and education program a Consumer Information Sheet, a toll free number for information, a website and a program to tag individual pieces of CCA lumber.

- In response to ongoing changes in the residential treated wood market, the wood treatment industry in Canada is making a transition away from the use of CCA to treat wood for use in residential applications by the end of 2003.

PMRA ARLA

COMPLIANCE AND REGIONAL OPERATIONS

Compliance with regulatory decisions and the PCPA and Regulations is a vital component of the Agency's business of pesticide risk reduction and sustainable pest management. The PMRA promotes, verifies, maintains and enforces compliance with the PCPA through consultations, inspections and investigations.

The National Pesticides Compliance Program (NPCP), developed annually, is based on national and regional compliance issues. It includes compliance programs that are focussed on three distinct target groups: pesticide companies that manufacture, import and sell products; pesticide distributors; and users of pesticides. Compliance is achieved through a network of PMRA regional officers and designated CFIA inspectors across Canada.

The Agency recognizes that it is important to target its activities effectively. Consequently, during the past five years, the PMRA has developed a business case approach that includes updated risk-based considerations for identifying candidates for compliance program areas and priorities. The candidate selection process takes into consideration the weight of evidence (real, suspected or anticipated); the extent of the issue (national, regional, provincial); and the impact of the issue on health and safety, the environment, the economy, and regulatory integrity if action is not taken. Candidates are then ranked, based on guiding principles, urgency, program priorities related to health and safety, re-evaluation, integrity of regulatory system, potential impact and barriers, and appropriate timing and resource requirements.

LABORATORY SERVICES

The PMRA Laboratory has provided ongoing and timely support to the NPCP by delivering analytical services for the detection of pesticide residues in a variety of agricultural and environmental samples. The expertise of the laboratory in mass spectrometry chemical identification has been important in providing analytical results to PMRA and non-PMRA programs, and aids in emergency situations. In addition, the PMRA laboratory has provided analytical services in support of registration decisions, specifically a product's compliance to the specifications upon which they were registered. Support may include the analysis of active ingredients, formulants or impurities, with a particular focus upon components of toxicological significance such as those addressed by the federal government's Toxic Substances Management Policy.

The PMRA laboratory has provided ongoing support to the inspection activities associated with certification for compliance of establishments with Good Laboratory Practice. To deliver these responsibilities, the laboratory has maintained scientific expertise and technical capability at the level required to provide an effective and efficient service to the PMRA. In addition, the PMRA laboratory has developed an average of five new analytical methodologies each year in response to anticipated needs. As part of maintaining expertise, laboratory staff have published results in a peer-reviewed journal and presented at conferences, as well as seeking opportunities to transfer technology and/or expertise. The PMRA laboratory has maintained its certification under the stringent ISO/IEC 17025 requirements, and sought opportunities to continuously improve the quality of the laboratory's analytical services.

Working Agreements and Partnerships

The PMRA regional managers and officers have a long and well established history of working with other federal agencies and provincial/territorial regulatory officials in the development and delivery of compliance programs. As regional representatives of the PMRA, regional officials routinely provide general pesticide regulatory information and exchange information on federal and provincial compliance programs and activities.

The PMRA has developed working relationships with all provinces and in many cases formal agreements that will be reviewed and revised, if needed, every three years. Collaboration with the CFIA is equally important. During the last five years, the PMRA finalized, with CFIA, a Memorandum of Understanding (and associated laboratory and regional operations sub agreements) that formalizes working relationships.

Compliance Promotion

During the past five years, the PMRA has worked on several initiatives to promote compliance with registration decisions and with the PCPA and Regulations. Compliance promotion includes a diverse range of activities such as compliance education, compliance outreach programs, and the support of industry stewardship programs.

Compliance Education through PMRA Publications

In order to promote compliance though education activities, the PMRA has developed several types of documents including, but not limited to Regulatory Directives, Pest Notes and Handouts. These documents are developed to explain the Agency's policy, guidelines and legislation to inform the public about the importance of compliance. Compliance promotion programs aim to educate, facilitate and promote compliance as well as communicate regulatory information.

One of the first and most important documents that was published during this period was Backgrounder B98-01, *Compliance and Enforcement Policy Guideline* (http://www.hc-sc.gc.ca/pmra-arla/english/pdf/bgr/bgr_b9801-e.pdf). This guideline provides information on the PMRA's policies on compliance and enforcement including the measures used by the PMRA to promote and enhance compliance with the PCPA, the principles established to ensure fair treatment of the regulated community, and the role of designated inspectors.

In 1999, the Agency published its advertising policy in Regulatory Directive DIR99-02, *Advertising Pest Control Products* (http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir9902-e.pdf), to inform registrants, agencies and others about advertising legislation. The PMRA's advertising policy is designed to protect health and safety and the environment, and to prevent deception and to advise industry and the public that an infringement of advertising legislation is serious.

The PMRA acknowledges the pesticide industry's efforts to guide and encourage registrants to comply with the letter and spirit of regulatory requirements. The Marketing Code of Standards developed by the Crop Protection Institute, now CropLife Canada, is an example of this type of initiative. This code encourages registrants to ensure their promotional efforts maintain and enhance the high ethical standards and image of industry.

In March 2000, an advisory entitled *Health Canada Advises the Public about Unregistered Silver Ion Releasing Devices for Pools and Hot Tubs* (http://www.hc-sc.gc.ca/english/protection/warnings/2000/2000_30e.htm) outlined the potential health hazards of silver ion releasing devices to sanitize pools and hot tubs. These products claimed to reduce or eliminate the need for chlorine or bromine for sanitizing pool or hot tub water. There are no silver ion releasing devices currently registered under the PCPA for this purpose, and they cannot legally take the place of sanitizing products containing chlorine or bromine. Four Pest Notes were published to inform consumers on proper pool and spa sanitation and encourage compliance.

In May 2000, a Health Canada Advisory alerted the public to a recall of Bear Pause Attack Deterrent. The manufacturer had substituted the active ingredient, capsaicin, with a synthetic form that had not been proven to be effective against bears. In February 2001, another Health Canada Advisory alerted the public about a voluntary recall of all Bearier Bear Repellent after the PMRA found problems with the spray mechanism, making it likely to malfunction when used, posing an unacceptable risk to users.

Compliance Outreach Programs

After a number of complaints about pesticide spraying in orchards near schoolyards, the British Columbia (B.C.) Region held meetings with the respective provincial agencies, fruit growers and school boards. An agreement was reached and procedure was developed outlining the responsibilities of the growers and the school boards for the timing and notification of spraying and the required safety measures. Other school districts were encouraged to develop similar policies.

An increase in termite infestations and treatments in the B.C. Interior brought numerous complaints from homeowners, pest control operators, the housing industry and regulatory officials. The B.C. Region and other key players formed a committee and held a workshop to promote awareness of the western subterranean termite. Participants learned how to identify, prevent and manage infestations, and the complaints have since stopped. Follow-up sessions will be scheduled as new control methods are developed.

From 1998 to 31 March 2003, PMRA regional officers have consulted with various stakeholders, including provincial extension agronomists, public health inspectors, customs brokers and Canada Customs and Revenue Agency officers, provincial environmental inspectors and the public on compliance activities, and have gathered and exchanged information on enforcement issues. PMRA regional officers have also been involved in supporting industry efforts to resolve compliance issues through stewardship initiatives and community outreach programs. Other compliance consultation activities have resulted in growers' increased knowledge and awareness of the PMRA's Minor Use Program and use of registered products for approved uses.

Information and education have been effective tools in securing conformity with the law and this activity has become an important component of all inspection programs and investigations.

SUPPORTING INDUSTRY STEWARDSHIP PROGRAMS

The Quebec Regional Office has worked extensively with the provincial regulatory officials, industry and other federal agencies to solve a persistent use of unregistered pesticides by the maple syrup industry. The goal was to have all stakeholders work in conjunction with the PMRA to obtain compliance. As a result, a provincial committee has been created and measures have been put in place by the involved producers association, provincial and federal agencies with significant improvements in compliance. PMRA compliance measures included prosecutions and the issuance of Administrative Monetary Penalties (AMPs), with the results being shared with industry, producers/users, the media and the public.

Following a 1998 joint investigation with Ontario's Ministry of the Environment on the misuse of a fungicide on tobacco, the Ontario Flue-Cured Tobacco Growers Marketing Board amended its regulations to make pesticide misuse a violation of the *Farm Products Marketing Act*.

A 1998 investigation on the misuse of streptomycin on tomatoes prompted the Ontario Vegetable Growers Marketing Board and the Ontario Food Processors Association to introduce a Pesticide Management Protocol for the tomato industry in 1999. The Protocol includes a provision for third party collection and analysis of samples for pesticide residues.

The Alberta Regional Office has been working with the provincial agriculture department and a vegetable cooperative to solve a compliance issue in the greenhouse vegetable industry. As a result, the cooperative developed a corporate policy that includes random testing of product throughout the season and a mandatory chemical notification program for growers. These procedures were adopted to ensure vegetables delivered to the cooperative are produced using only registered pesticides and labelled uses.

In 2002, the B.C. Regional Office in partnership with the Mushroom Marketing Commission, mushroom industry as well as provincial and federal agencies developed a Pesticide Safety Program for mushroom growers to resolve compliance issues in the industry. Compliance with all pesticide regulations is one of the criteria of this program.

COMPLIANCE INSPECTION PROGRAMS

During the past five years, more than 180 separate Inspection Programs have been conducted, designed to determine the level of compliance of users, distributors and registrants of pest control products with specific terms and conditions of registration and provisions of the PCPA and Regulations. The results and findings of these programs were used to determine if there was need for subsequent monitoring or enhanced vigilance as part of surveillance inspections.

Surveillance inspections were conducted to target specific individuals or groups for follow-up on previous findings or concerns. There have been thirty-three surveillance programs over the last five years. Surveillance programs have included, for example, inspection activity focussed on pesticides used by growers of ginseng, greenhouse cucumber, raspberry, and cherry; maple syrup producers; and salmon aquaculture farms.

Since 2001, there has been three contingency monitoring or surveillance inspection programs put in place in response to major pesticide problems or health and safety concerns that arose throughout the year after the NPCP plan had been set.

Between 1998 and 31 March 2003, there have been 122 user based, 18 distributor based and 42 registrant based compliance programs. During the more than 180 inspection programs, over 8500 inspections were conducted and more than 6200 sample analyses were completed, including over 5900 residue analyses and more than 800 formulation analyses.

A significant aspect of the PMRA's post registration compliance role is to verify that products are being used legally and according to label instructions. Many inspection programs have focussed on unlabelled uses of registered products and use of unregistered pesticides. Inspection programs of user groups (i.e., raspberry, blueberry, veterinary clinics, log home builders, fruit packing surveys, elevator survey, mushroom survey) have asked questions about the products used and on which crop and for what pest; protective equipment on hand and used; how pesticides are applied and the frequency and timing; how excess spray solution is disposed and what is done with empty pesticide containers; pesticide storage; and where growers get information on product use. The outcome of user inspection programs can result in an enforcement response to any infractions of the PCPA and Regulations or a referral to the responsible agency or authority.

When there has been a major change in the directions for use on a product's label, for example through re-evaluation, the PMRA has followed up with a user-targeted program to ensure that the users are aware of and comply with the changes. Virtually every program that has been run from 1998 to 2002 has been designed to ensure at least some aspect of the label directions are followed.

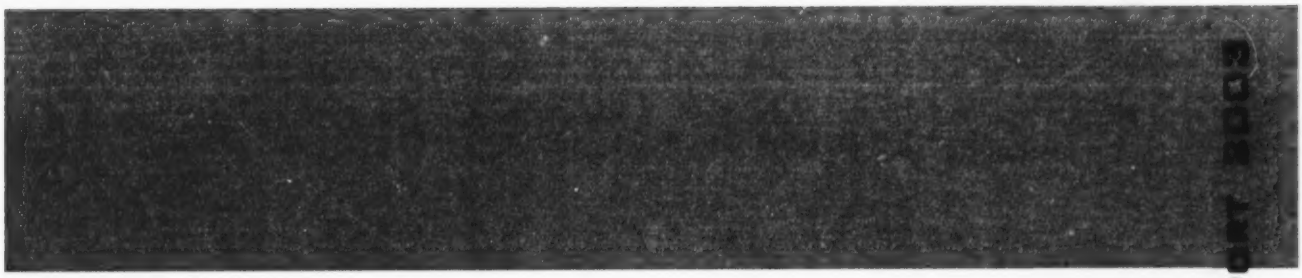
Investigations and Enforcement

When the situation warrants and a suspected violation of the PCPA or Regulations is detected, the PMRA has a range of enforcement response tools that may be applied. Enforcement actions in response to PCPA violations include the following: warning or prosecution of violators; seizure and detention, forfeiture, and denial of entry into Canada; or cancellation or suspension of the registration status of the product; or a combination of these actions. The nature and severity of an enforcement response will vary depending on the evidence and facts in a particular situation and will be determined based on the individual circumstances and the expectations of resulting compliance.

In the spring of 2001, the PMRA enhanced its enforcement program by expanding the range of enforcement options to include AMPs. The *Administrative and Monetary Penalties Act* (AMPs Act) establishes a system of penalties for the enforcement of the PCPA as well as seven Acts administered by AAFC. The AMPs Act has provided the PMRA with another type of enforcement response, when earlier Agency interventions have not resulted in compliance or when circumstances are sufficiently serious that other enforcement options are not appropriate. Under the AMPs Act, warnings and monetary penalties can be imposed in lieu of or in addition to other sanctions available under the PCPA and Regulations.

Because the AMPs Act provides for sanctions to be imposed by government officers rather than through the separate and independent judiciary system, the legislation requires strict adherence to prescribed rules and time lines. The AMPs Act has established various process options with set time lines that must be followed by both the government and the violator to assure consistent actions. As a result, Standard Operating Procedures were developed to guide PMRA Regional and Headquarters staff.

Extensive efforts have also been invested in the redesign and implementation of the Compliance Investigation tracking database. An AMPs database was also developed and is being used to electronically store AMPs enforcement files. In 2001, PMRA inspectors were designated and delegated for issuing AMPs and an AMPs Brochure was published explaining the AMPs processes as administered by the PMRA. Since



the implementation of AMPs for PCPA violations in the spring of 2001, over 50 AMP Notice of Violations have been initiated or completed. The first Notice of Violation was issued in January 2002.

From 1998 to 31 March 2003, over 2900 investigations were conducted, resulting in approximately 2500 enforcement response actions, including product detention, denial of product entry into Canada, education (written and oral), AMPs or AMP warnings and prosecutions. The majority of violations were minor in nature; many violations were dealt with and corrected using education. However, from 1998 to 31 March 2003, the Agency has been successful with 17 criminal prosecutions.

Measuring and Reporting Compliance with PCPA and Regulations

To be able to assess whether efforts made through the NPCP are achieving anticipated results, the PMRA's compliance and enforcement activities have been developed with a focus on solving compliance problems rather than inspecting for levels of compliance.

To improve information about compliance status, the Agency has initiated efforts to gather monitoring information from other sources, such as other federal and provincial departments, to identify potential compliance problems. More recently, the Agency has been working on expanding current discussions with comparable Canadian and international organizations that are responsible for promoting, inspecting and enforcing compliance to determine how, with finite resources, they target activities and how they measure user compliance.

The PMRA has also recognized that reliable information and reporting on compliance is important to build and maintain public confidence in the federal pesticide regulatory system under the PCPA. The Agency has taken steps towards improving its current reporting of results, and has also commenced the development of a framework for generating a report of compliance activities to be posted on the Agency website.

CONTINUOUS IMPROVEMENT

PROCESS IMPROVEMENT

To streamline and improve efficiency, the Agency analyzed the work flow—or the stages of a submission—as it moves through the evaluation process.

To ensure the most efficient use of evaluator time, data submissions must be complete. Accordingly, the Agency provides a presubmission consultation with industry information on the proposed product provided by applicants. This ensures they are familiar with the data requirements and minimizes the need to request additional data once the review begins. For products entering the Joint Review Program, the PMRA and the USEPA carry out joint presubmission consultations with the applicants from both countries. In addition, the PMRA regularly schedules a Canadian pesticide registration course to help registrants and other stakeholders understand the process of pesticide regulation in Canada as well as to understand how a submission should be put together.

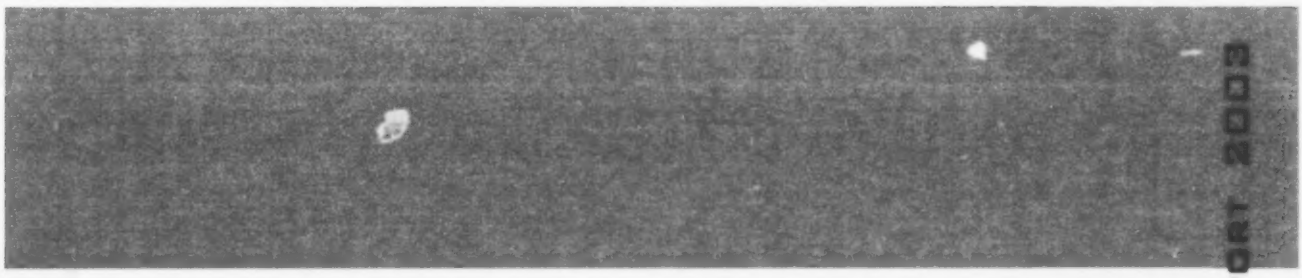
During the past five fiscal years the Agency has streamlined its review processes, prepared standard operating procedures and trained staff in the more efficient processes. This initiative led to the introduction of team leads to steward the submission according to the schedule and standard time lines.

In 1999, the PMRA introduced a new tracking system, in time for the Y2K deadline, which helps the Agency better control the process and measure the submission review performance.

SINGLE WINDOW APPROACH FOR DISINFECTANTS/SANITIZERS

Until September 2001, the regulation of disinfectants used on indoor surfaces was primarily based on two considerations: where they would be used and the purpose for using them. Disinfectants used in health care or food processing facilities were considered drugs and regulated under the *Food and Drugs Act*. Sanitizers that were used in health care or food facilities, disinfectant and disinfectant/sanitizer combination products used in industry, in homes or in institutions such as schools were considered pesticides under the PCPA.

Stakeholders wanted a more streamlined process and a consolidation of regulation under one act. The PMRA and the Therapeutic Products Directorate of Health Canada conducted extensive consultations with industry and other stakeholders, and considered the options to create a single regulatory window. The Therapeutic Products Directorate now provides a single window for the review of applications under the *Food and Drugs Act*. An amendment to the Pest Control Products Regulations was completed in September 2001.



The regulatory amendment substantially reduces regulatory duplication between the PCPA and the *Food and Drugs Act*, by exempting disinfectant uses of a control product from the PCPA. Sanitizer uses associated with exempt disinfectant uses of a control product are also exempted from the PCPA. Use of a control product in a swimming pool or spa or use as a preservative or slimicide are not exempt. This is part of the government's plans to reform legislation and streamline regulatory processes wherever possible.

More Efficient Label Review Process

In 1998, a pilot project to issue a certificate of registration on the basis of a version of the label other than a final printed label was initiated as a result of the recommendations of the Joint Industry–PMRA Label Working Group. The success of this pilot project, along with other labelling changes (e.g., bilingual labelling), led to the development of an updated label review process in the PMRA as described in *Label Process Changes Part 1: Overview* (http://www.hc-sc.gc.ca/pmra-arla/english/pdf/lps/overview-e.pdf) and *Part 2: Guidance for Industry* (http://www.hc-sc.gc.ca/pmra-arla/english/pdf/lps/guidance-e.pdf). Among the changes implemented in the updated process are:

As of 1 January 2003:

- A certificate of registration is issued on the basis of a text only label.
- All certificates of registration must be issued on the basis of a bilingual text label (refer to *Canada Gazette Part II*, Vol. 135, No. 26, 19, 2001-12-19).

As of 1 July 2003:

- Labels must be provided to the PMRA in pdf normal format only; hard copy labels are no longer required.

The marketplace label (formerly referred to as the "final printed label") is still required at registration renewal, along with the electronic text label in both official languages.

IMPROVED TIME LINES FOR REVIEW OF SUBMISSIONS

The PMRA was encouraged by EMAC and other parties to shorten time lines for certain types of Category B submissions. This resulted in Regulatory Note REG99-01, *Category C Submission Efficacy Reviews*, which was then a revised version in order to clarify certain criteria, producing REG2002-04, *Category C Submission Efficacy Reviews* (http://www.hc-sc.gc.ca/pmra-arla/english/pdf/reg/reg2002-04-e.pdf). The following types of submissions that require only efficacy/value data are now eligible as Category C submissions, with shorter time lines:

- a decreased use rate
- change in level of control (e.g., from suppression to control)
- tank mixes:
  - non-food uses
  - food uses where the application is not intended for application to a transgenic crop
  - addition of pest(s) to a maximum of two

The Agency's performance standard for these 'fast track' Category C submissions is 150 days (verification, screening and review). The previous time standard was 417 days.

EXPANSION OF NOTIFICATION AND NON-NOTIFICATION CATEGORIES

Regulatory Directive DIR2001-04, *Notification/Non-Notification* (http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir2001-04-e.pdf), published in April 2001 reduces the regulatory burden for applicants. It defines 16 types of changes that will be treated the same, or similarly, in Canada and the U.S. For five types of changes, the PMRA will perform a more in-depth review than the USEPA (i.e., notification instead of non-notification), based on potential hazards, process differences or policy considerations. For four other types of changes, such as correcting typographical errors, the PMRA has proposed that registrants make the changes without notification. The plan is based on Agency experience and expertise in reviewing these types of changes under the current amendment process.

This initiative furthers harmonization by adopting many of the items currently accepted by the USEPA as either notification or non-notification. The program may be expanded to include additional USEPA items. Developing a similar approach to notification/non-notification is consistent with the goals and objectives of the North American Initiative under NAFTA.

Increased Efficiency for Industry and Agency through Electronic Submission and Evaluation

An important part of this effort has been the development of electronic tools to improve data submission and review. The submission process has been broken down into three parts:

- electronic assembly, an industry need;
- electronic evaluation, a regulatory need; and
- electronic archiving, an industry and a regulatory need.

The main focus has been electronic assembly and evaluation. How a submission is electronically assembled determines the efficiency and flexibility of the review. To take advantage of electronic assembly and review, registrants have established workflow processes that support both paper-based and electronic assembly.

A series of pilots have been launched in cooperation with the USEPA and the pesticide industry to investigate approaches to electronic data submission and review. The results are extremely encouraging.

The PMRA received the world's first interactive electronic dossier for a research permit and a full submission, and North America's first Computer Aided Dossier and Data Supply (CADDY) submission. PMRA evaluators tested various software options and assessed efficiency gains of the CADDY format as well as an interactive PDF format that could be assessed through a web browser over paper submissions. The PDF format provided a 23% gain in efficiency. Also, PMRA evaluators found the CADDY tool, initially designed as an archiving standard, was not flexible enough for electronic reviews.

The PMRA presented its preliminary findings on the research permit pilot at the 21 September 1998 CADDY Joint Data Steering Group meeting. These findings are the same for the full submission as for the research permit.

PMRA evaluators reported that some keys to increasing efficiency were the ability to re-use "tombstone" data (such as tables), the provision of Tiers II and III in an editable format, consistent template formats for screening and evaluation, and formats for creating documents such as tables.

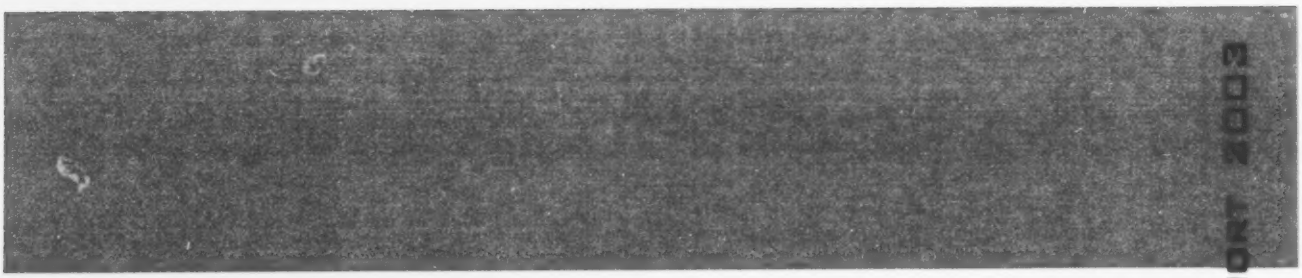
Under NAFTA, Canada, the U.S. and Mexico are working together to test electronic solutions including interactive browser-deployed submissions with data in PDF format. For years, pesticide regulators have used a patchwork of largely paper-based systems to compile, update and store industry data, making it difficult for the various agencies and pesticide companies to work together. A major stumbling block in the development of an electronic solution is the lack of compatibility in the software used by different companies. The PMRA addressed the issue with the Electronic Dossier, Delivery and Evaluation (EDDE) program, an approach to achieving a standard format to harmonize the review process and provide an electronic work capability between reviewers and industry. The program saves time and allows for improving the quality of reviews. Both industry and regulators now benefit from this approach. EDDE is currently supported by pilot testing and reference material on a supporting system EDDENet. The key on-line guidance documents on electronic submission and review are listed below.

Guidance to Applicants for Preparing Electronic Submissions, Part I: An Overview (http://www.hc-sc.gc.ca/pmra-arla/english/pdf/reg/reg2001-06-e.pdf) shares information and describes how applicants may participate in joint Agency–industry electronic pilot projects.

Guidance to Applicants for Preparing an Electronic Submission: Part II, Guidance for Industry During Pilot Stage (http://www.hc-sc.gc.ca/pmra-arla/english/pdf/edde/edde2001-01-e.pdf) provides background and guidance on the PMRA's pilot project to investigate requirements for the delivery of electronic dossiers.

Guidance to Applicants for Preparing an Electronic Submission: Part III, Guidance of Evaluator Functional Requirements for Electronic Evaluation (http://www.hc-sc.gc.ca/pmra-arla/english/pdf/edde/edde2001-02-e.pdf) provides information about evaluator needs during electronic evaluation.

Guidance to Applicants for Preparing an Electronic Submission: Part IV, Guidance on Preparation of Documents for Electronic Exchange (http://www.hc-sc.gc.ca/pmra-arla/english/pdf/edde/edde2001-03-e.pdf) provides guidance on the creation and the exchange of documents to minimize software incompatibility issues.



The Agency's commitment to electronic initiatives (including EDDE) are aligned with the federal Government's On-line initiative, and are part of the Agency's effort to achieve a 40% efficiency gain in the review of complex submissions, through international harmonization, re-engineering of business processes and the use of enabling technologies, and joint reviews.

Single Window Approach for Contact

The bilingual Pest Management Information Service, available since 1984, provides information on pesticide regulation and registered pesticides. The designation of the Pest Management Information Service as a "Single Window" for all inquiries to the Agency is intended to facilitate an efficient, consistent and timely response to all inquiries. Pest Management Information Service Information Officers will either respond to inquiries directly or redirect the inquiry to appropriate PMRA subject area experts.

General inquiries regarding compliance with product labelling may be posed through the "Single Window". Regional officers may be directly contacted when making specific inquiries or complaints regarding misuse, mislabeling, importation, sales, advertising or the National Pesticides Compliance Program. Scientific questions will be directed to scientific staff. When the response to an inquiry requires input from several PMRA staff members, a coordinator will be appointed as an on-going point of contact for the inquirer to ensure a timely and coordinated agency response.

The Pest Management Information Service completed the first phase of the Service Improvement implementation process, which included conducting client satisfaction surveys and establishing baselines for service delivery. Results showed that clients were highly satisfied as the Information Service received an excellent score of 4.6 on a 1–5 point Likert Scale. Further, based on client feedback, the Information Service has implemented important changes to its service, which include the following:

- The telephone voice-mail menu has been modified and improved with added features to increase its user-friendliness;
- It is now easier to find the PMRA website from the main Health Canada website through the use of a link, thus allowing PMRA information to be more accessible.

As part of PMRA's commitment to improving service to its clients, and in an ongoing effort to continue providing fast, friendly and accurate information, the Information Services will soon be conducting a follow up survey.

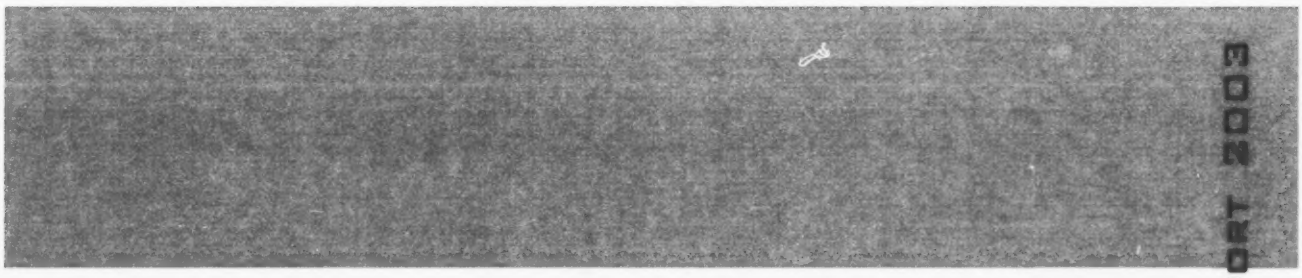
CONTINUOUS LEARNING PROGRAM

Shortly after the PMRA was established in 1995, an operational training and development program plan was launched as an integral component of the PMRA strategic framework and business plan. The PMRA Continuous Learning Program is now an established part of the Agency and a key driver in maintaining a learning culture. The Continuous Learning Program provides focused cost-effective learning opportunities for PMRA employees. The Continuous Learning Program objectives include the following:

- to provide for the orientation of new staff members to ensure that they achieve a high level of job competency in as short a time as possible;
- to provide ways for all employees to maintain their skills as well as develop additional and improved skills to meet the new and evolving challenges of their jobs; and
- to ensure the availability of programs that will prepare interested staff moving laterally into new jobs, assuming more senior positions in their own field or moving into supervisory or management positions.

Since its inception, the PMRA Continuous Learning Program has grown to eight staff that manage, develop and coordinate operational/scientific/professional learning and development for staff; staff orientation; staff and management development programs; internal communication/learning activities as well as training for stakeholders (pesticide industry, provincial government, etc.). Personal and organizational learning plans are developed on an annual basis and serve as the basis for program delivery. Quarterly and annual learning reports track progress and performance.

Over the last five years, staff training has been intensive with the average number of training days/employee/year ranging from 5.1–6.0 days/employee, with an average of 5.4 days/employee. In general, 40% of the learning activities are on core competencies and 60% are on operational, scientific, and professional competencies. Core competencies include orientation; communication skills; information technology; interpersonal skills; office/business skills and management skills. Operational, scientific, and professional learning includes in-house courses, field tours, conferences, seminars, information sessions as well as external training.



Some examples of the different types of learning offered in the last fiscal year are:

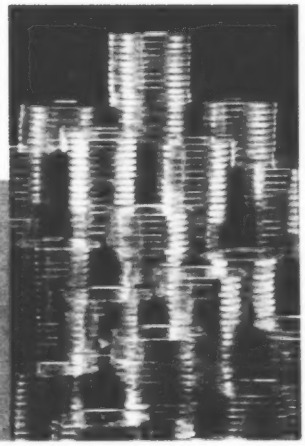
- Orientation modules for new PMRA staff;
- good laboratory practices;
- field tours to provide learning on pesticide application practices and use patterns, including a minor use greenhouse tour in Southern Ontario, and orchard spraying tours of small and large seed treatment facilities; and
- a seminar from Department of National Defence on "Battling the Bugs".

One recent key initiative was the launch of a science-based development program for biologist and chemists, a first in the Public Service. The program provides a learning environment that leads to career advancement for the participants in a planned and consistent manner. It is based on competencies for the different job levels and promotions are based on individual merit, without competition as the program participants meet the required competencies for the next level.

Recruitment Initiative

The Recruitment Initiative was a joint project created by the Human Resources Operational Unit and the PMRA. The initiative resulted from the need to hire a number of qualified individuals to meet the increasing demands on the Agency resulting from activities required under the new PCPA. The initiative was based on anticipated growth ratios within the PMRA. With the collaboration of the Agency management teams and Human Resources, numerous staffing actions were completed and approximately 50 new qualified employees were hired into the Agency.

Resources



The PMRA is funded by public funds (i.e., appropriations) and external fees resulting from cost recovery regulations. Public funds represent approximately 80% of the Agency's resource base. Revenues from cost recovery make up the other 20%. The proportion of public funds has increased from 70% in 1998–1999 to 80% in 2002–2003. This is due to the fact that the government has funded new activities and that external revenues have remained relatively stable over the same period. The tables below provide a five year history of expenditures by business line and revenues by source.

Pest Management Regulatory Agency
Resource Summary

Gross Expenditures

	1998 / 99 Actuals		1999 / 00 Actuals		2000 / 01 Actuals		2001 / 02 Actuals		2002 / 03 Actuals	
	F.T.E.'s	Total Operating $M	F.T.E.'s	Total Operating $M	F.T.E.'s	Total Operating $M	F.T.E.'s	Total Operating $M	F.T.E.'s	Total Operating $M
BL1 - New Product Evaluation	157 (50%)	12.4 (47%)	149 (46%)	11.3 (43)	156 (46%)	12.7 (43%)	180 (49%)	14.5 (46%)	216 (51%)	18.7 (49%)
BL2 - Registered Product Evaluation	32 (10%)	2.7 (10%)	50 (16%)	4.0 (15%)	74 (22%)	6.3 (21%)	80 (22%)	6.8 (21%)	89 (21%)	8.2 (21%)
BL3 - Compliance	85 (27%)	6.3 (24%)	78 (24%)	5.9 (22%)	79 (23%)	6.1 (21%)	81 (22%)	6.7 (21%)	83 (20%)	7.2 (19%)
BL4 - Sustainable Pest Management	10 (3%)	0.9 (3%)	13 (4%)	1.1 (4%)	16 (5%)	1.3 (4%)	15 (4%)	1.3 (4%)	22 (5%)	2.0 (5%)
BL5 - Improvements	31 (10%)	4.1 (15%)	31 (10%)	4.3 (16%)	16 (5%)	3.1 (10%)	10 (3%)	2.6 (8%)	15 (3%)	2.4 (6%)
TOTALS	315 (100%)	26.3 (100%)	321 (100%)	26.6 (100%)	341 (100%)	29.5 (100%)	367 (100%)	31.9 (100%)	424 (100%)	38.5 (100%)

Revenues*

	1998 / 99 Actuals	1999 / 00 Actuals	2000 / 01 Actuals	2001 / 02 Actuals	2002 / 03 Actuals
Application Fees	3.4	3.4	2	3.1	2.9
Maintenance Fees	4.4	5.1	5	4.9	4.7
Total	7.8	8.5	7	8	7.6
Net Expenditures	18.5	18.1	22.5	23.9	30.9

* The Agency charges one time application fees for the review of applications for the registration of pestices and an annual maintenance fee per registered product for the right to manufacture or sell a product in Canada

PMRA ARLA

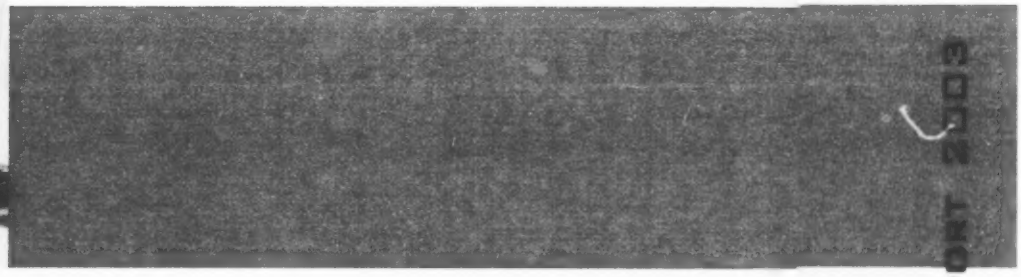
COMMUNICATING WITH OUR STAKEHOLDERS

The PMRA is committed to an open, transparent and participatory process for pesticide regulation. The Agency seeks the advice of its advisory bodies and solicits public comment on new policies and programs, on major pesticide registration decisions and on re-evaluation decisions. Information on the PMRA's extensive involvement in international pesticide-related efforts, notably the NAFTA TWG and the OECD's Pesticide Program, is circulated broadly and regularly. In addition a consultation meeting with stakeholders is held prior to the yearly full meeting of the NAFTA TWG.

In 1998–1999, the Agency published 45 regulatory and other documents. This increased to 81 documents in 1999–2000, primarily due to the introduction of Pest Notes, a series of consumer information articles on common pest problems and solutions. In 1998–1999, more than 330 000 pages of information were requested from our website, with 45% of the requests coming from within Canada. That number more than doubled to 727 000 pages in 1999–2000, with 55% of requests coming from within Canada.

Since 1999, the Agency has published approximately 100 regulatory and other documents annually, including information on proposed new product registrations and re-evaluations of existing pesticides. Also, the PMRA's library of consumer materials has grown to meet public demand for information on issues such as mosquitos and West Nile virus, integrated pest management and healthy lawn care. In 2002, the public requested more than 248 000 pages of information from the PMRA website.

The PMRA's website at www.hc-sc.gc.ca/pmra-arla contains all current PMRA publications including a wide range of information for industry and the general public. A notification service that provides a message when a new document is placed on the web is available on the site. The PMRA Publications Coordinator can be reached at pmra_publications@hc-sc.gc.ca.



As discussed in Single Window Approach for Contact, the Pest Management Information Service provides information on pesticide regulation and registered pesticides. All pest management inquiries should be made to this service.

Pest Management Information Service–Pest Management Regulatory Agency
2720 Riverside Drive
Ottawa, Ontario K1A 0K9
Telephone: 1 800 267-6315 or (613) 736-3799
Fax: (613)736-3798
E-mail: pmra_infoserv@pmra-arla.hc-sc.gc.ca

LIST OF ABBREVIATIONS

AAFC	Agriculture and Agri-Food Canada
AMC	Agency Management Committee
AMP	administrative monetary penalty
AMPs Act	*Administrative and Monetary Penalties Act*
B.C.	British Columbia
CADDY	Computer Aided Dossier and Data Supply
CCA	chromated copper arsenate
CFIA	Canadian Food Inspection Agency
EDDE	Electronic Dossier, Delivery and Evaluation
EMAC	Economic Management Advisory Committee
EU	European Union
FTE	Full-time Equivalent
FPT Committee	Federal/Provincial/Territorial Committee on Pesticides and Pest Management
GLP	Good Laboratory Practice
ICM	Integrated Crop Management
IFP	Integrated Fruit Management for a Sustainable Production
IPM	Integrated Pest Management
IR-4	United States Department of Agriculture's Interregional Research Project Number 4
MOSP	*Management of Submissions Policy*
MRL	maximum residue limit
NAFTA	North American Free Trade Agreement
NAFTA TWG	North American Free Trade Agreement Technical Working Group on Pesticides
NPCP	National Pesticides Compliance Program
OECD WGP	Organisation for Economic Co-operation and Development Working Group on Pesticides
PCPA	*Pest Control Products Act*
PDF	portable document format
PIC	Prior Informed Consent
PMAC	Pest Management Advisory Council
PMRA	Pest Management Regulatory Agency
PRDD	Proposed Regulatory Decision Document
TSMP	Toxic Substances Management Policy

URMULE	User Requested Minor Use Label Expansion
URMUR	User Requested Minor Use Registration
U.S.	United States
USEPA	United States Environmental Protection Agency

REFERENCES

The following is a list of references (primarily websites) and the information available at these locations.

North American Initiative

This document provides the conceptual framework for the work of the NAFTA TWG.

Regulations Amending the Pest Control Products Regulations

For more information on label improvements, see the above regulations published on 19 December 2001 in the *Canada Gazette* Part II.

http://www.hc-sc.gc.ca/pmra-arla

The PMRA's website contains all current PMRA publications including a wide range of information for industry and the general public, such as the PMRA publications that detail 53 of 61 active ingredients addressed through the current re-evaluation program.

http://www.hc-sc.gc.ca/pmra-arla/english/intern/intern-e.html

For more information on NAFTA and OECD projects.

http://www.oecd.org/ at http://www.eddenet.ca or http://www.hc-sc.gc.ca/pmra-arla

For more information on submission formats (*Guidelines and Criteria for Industry for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for Plant Protection Products and their Active Substances in Support of Regulatory Decisions in OECD Countries*).

http://www.hc-sc.gc.ca/pmra-arla/english/advbod/pmac-e.html

For more information on PMAC.

http://www.hc-sc.gc.ca/pmra-arla/english/advbod/emac-e.html

For more information on EMAC.

http://www.hc-sc.gc.ca/pmra-arla/english/fpt/fpt-e.html
For more information on the FPT Committee.

http://www.hc-sc.gc.ca/pmra-arla/english/pubs/fqpa-e.html
For more information on a number of the science policies published by the PMRA.

http://www.ec.gc.ca/toxics/en/index.cfm
For more information about the TSMP.

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir9903-e.pdf
For more information about the PMRA's strategy for implementing the TSMP.

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir2002-02-e.pdf
For more information on the Reduced-risk Program.

http://www.hc-sc.gc.ca/pmra-arla/english/intern/oecd-e.html
For more information on international efforts to harmonize common core data requirements.

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir9802a-e.pdf
For more information about the PMRA's Regulatory Directive DIR98-02, *Residue Chemistry Guidelines*.

http://www.hc-sc.gc.ca/pmra-arla/english/pubs/pro9804-e.html
For more information about the PMRA's proposed harmonized *Postapplication Exposure Monitoring Test Guidelines*.

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/pro/pro2000-04-e.pdf
For more information about the PMRA's Regulatory Proposal PRO2000-04, *Formulants Policy*.

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir9804-e.pdf
For more information about the PMRA's *Chemistry Requirements for Registration of a Technical Grade of Active Ingredient or an Integrated System Product*.

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir9803-e.pdf
For more information about the PMRA's *Chemistry Requirements for the Registration of a Manufacturing Concentrate or an End-Use Product Formulated from Registered Technical Grade of Active Ingredients or Integrated System Products.*

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir9906-e.pdf
For more information about the PMRA's *Voluntary Pesticide Resistance-Management Labelling Based on Target Site/Mode of Action.*

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir9801-e.pdf
For more information on GLP requirements (Regulatory Directive DIR98-01, *Good Laboratory Practice*).

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir9805-e.pdf
For more information about the PMRA's Regulatory Directive DIR98-05, *Chemical Pesticides Research Permit Guideline.*

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/pro/pro2002-02-e.pdf
For more information about the PMRA's *Guidelines for the Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals.*

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir2001-02-e.pdf
For more information about the PMRA's *Guidelines for the Registration of Microbial Pest Control Agents and Products.*

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/hlawns/hl-GovtResp-e.pdf
For an overview of the PMRA's pesticide use reduction policy.

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/fact/fs_ipmsealice-e.pdf
For a fact sheet relating to the use of integrated pest management of sea lice in aquaculture.

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/spm/spm_s9601-e.pdf
For a document on the use of IPM to control late blight on potatoes.

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/spm/spm_s9602-e.pdf
For the corresponding fact sheet on the use of IPM to control late blight on potatoes.

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/hlawns/hl-ActionPlan-e.pdf
For more information on the FPT Action Plan on Urban Use Pesticides.

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/fpt/ciwg/propdoc-e.pdf
For more information on the public consultation conducted by the provinces and the territories, *Proposal for a Harmonized Pesticide Classification System for Canada*.

http://www.healthylawns.ca/english/html/hg-e_flash.shtml#flash
For a copy of the PMRA's *Healthy Lawn Tips* and other related publications.

www.healthylawns.net
For the Healthy Lawns website, which contains information on reduced risk pest management and pest prevention strategies for lawns and turfgrass.

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/pro/pro9601-e.pdf
For more information on the responsibilities, time lines and performance standards outlined in the *Management of Submissions Policy* (MOSP).

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/nafta/naftajr/nafta-jr-pest-e.pdf
For more information on the *NAFTA Technical Working Group on Pesticides Revised Procedures for Joint Review*.

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/nafta/naftajr/nafta_jr_micro-e.pdf
For more information on the updated procedures under the Joint Review process for microbial pesticides or arthropod semiochemicals (including pheromones).

http://www.hc-sc.gc.ca/pmra-arla/english/pubs/jnt_rev-e.html
For more information on joint review activity, refer to the regular reports published on the PMRA website.

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir9905-e.pdf
For more information on the URMUR program.

http://www.hc-sc.gc.ca/pmra-arla/english/pubs/urmule-e.html
For more information on the URMULE program.

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir2001-03-e.pdf
For more information on the PMRA's re-evaluation program (*PMRA Re-evaluation Program*).

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/bgr/bgr_b9801-e.pdf
For more information on the PMRA's policies on compliance and enforcement including the measures used by the PMRA to promote and enhance compliance with the PCPA, the principles established to ensure fair treatment of the regulated community and the role of designated inspectors (Backgrounder B98-01, *The Compliance and Enforcement Policy Guideline*).

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir9902-e.pdf
For more information on the PMRA's advertising legislation (Regulatory Directive DIR99-02, *Advertising Pest Control Products*).

http://www.hc-sc.gc.ca/english/protection/warnings/2000/2000_30e.htm
For more information on the potential health hazards of silver ion releasing devices to sanitize pools and hot tubs (*Health Canada Advises the Public about Unregistered Silver Ion Releasing Devices for Pools and Hot Tubs*).

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/lps/overview-e.pdf
http://www.hc-sc.gc.ca/pmra-arla/english/pdf/lps/guidance-e.pdf
For more information on the PMRA's label review process *(Label Process Changes Part 1: Overview* and *Part 2: Guidance for Industry*).

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/reg/reg2002-04-e.pdf

For more information on the eligibility, criteria and procedures for acceptance of submissions as "fast track" efficacy reviews (Regulatory Note REG2002-04, *Category C Submission Efficacy Reviews*).

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir2001-04-e.pdf

For more information on the 16 types of changes that will be treated the same, or similarly, in Canada and the U.S. (Regulatory Directive DIR2001-04, *Notification/Non-Notification*).

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/reg/reg2001-06-e.pdf

For more information on how applicants may participate in joint Agency–industry electronic pilot projects (*Guidance to Applicants for Preparing Electronic Submissions, Part I: An Overview*).

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/edde/edde2001-01-e.pdf

For more background and guidance on the PMRA's pilot project to investigate requirements for the delivery of electronic dossiers (*Guidance to Applicants for Preparing an Electronic Submission: Part II, Guidance for Industry During Pilot Stage*).

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/edde/edde2001-02-e.pdf

For more information about evaluator needs during electronic evaluation (*Guidance to Applicants for Preparing an Electronic Submission: Part III, Guidance of Evaluator Functional Requirements for Electronic Evaluation*).

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/edde/edde2001-03-e.pdf

For more guidance on the creation and the exchange of documents to minimize software incompatibility issues (*Guidance to Applicants for Preparing an Electronic Submission: Part IV, Guidance on Preparation of Documents for Electronic Exchange*)

http://www.hc-sc.gc.ca/pmra-arla/english/pdf/cost/rias-e.pdf

For more information on the considerations of the potential influence of the risk reduction policy on the cost-recovery fee structure.